Human medicines: scope of regulation

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Consolidation of Medicines Legislation (2012)

Until August 2012, UK medicines legislation comprised the Medicines Act 1968 (the 1968 Act), around 60 principal SIs and around 130 amending SIs, which reflected developments in pharmaceuticals, wholesale trade, regulatory practice and European harmonisation. The view of the Medicines and Healthcare products Regulatory Agency (MHRA) was that the law had become fragmented and ‘potentially impenetrable for users’ and delivered a legislative framework that was ‘fragmented, complex, poorly structured and in places obsolete’. Hence, a consolidation of medicines legislation was undertaken, leading to the production and enactment of the Human Medicines Regulations 2012. These Human Medicines Regulations (HMRs) repealed, revoked or re-enacted most existing UK legislation regulating the authorisation, sale and supply of medicinal products for human use and consolidated their effect in one place and in rationalised form.

The Human Medicines Regulations 2012 leave parts of the 1968 Act in place, principally Part IV of the Act, which deals with the registration and conduct of pharmacies (chapter 5). Also retained are certain powers to make secondary legislation in areas that fall outside the scope of Directive 2001/83/EC (the Directive). The Human Medicines Regulations 2012 provide that medicines may be supplied to the public only from pharmacies, except those medicines which can with reasonable safety be sold without the supervision of a pharmacist. The Regulations also cover matters relating to the labelling of medicines, the containers in which they are supplied and the manner in which their sale is promoted, whether by advertisement or oral representation.

1MHRA (2011) Impact Assessment No. 4018
2MHRA (2012) Explanatory Memorandum to the Human Medicines Regulations 2012
3Human Medicines Regulations SI 2012 No. 1916
Certain pieces of medicines legislation have not been consolidated, including that concerned with clinical trials, the administration of radioactive medicinal products and fees charged by the MHRA for the administration of procedures under the provisions. Various orders made under section 62 of the Act to prohibit the sale, supply and importation of products containing particular substances will also remain in force along with section 62, because prohibitions of this sort are outside the scope of the Directive.

Section 104 of the 1968 Act provides for an Order to be made for the Human Medicines Regulations 2012 or the Clinical Trials Regulations to be applied to any article or substance which is not a medicinal product but is made wholly or partly for a medicinal purpose. In the past, Orders have been made in respect of surgical ligatures and sutures, dental filling substances, contact lenses and associated substances, and intrauterine contraceptive devices. However, since 1994, these substances have been considered to be medical devices rather than medicines and are now controlled under Medical Devices Regulations (see under Medical devices below).

Section 105 of the Act provides for an Order to be made for the HMRs or the Clinical Trials Regulations to be applied in respect of any substance which (a) is used as an ingredient in the manufacture of a medicinal product or (b) is capable of causing danger to the health of the community if used without proper safeguards. The order may specify which parts of the Act are to apply. Some substances used as ingredients in the manufacture of medicinal products, and certain other substances, have been controlled by orders of this kind (see appendix 1).

The Human Medicines Regulations 2012 repeal section 10(7) of the Medicines Act 1968 altogether. This section formerly exempted pharmacists from the need for a wholesale dealer’s licence if wholesale dealing formed only an inconsiderable part of their business, but was not compatible with the Directive (chapter 10).

Since the Medicines Act 1968 remains partially in force, it should be read in conjunction with the Human Medicines Regulations 2012. References to Parts, Regulations and Schedules in this chapter relate to the Human Medicines Regulations 2012 and those to sections to the Medicines Act 1968, unless otherwise stated.

Neither the 1968 Act nor the Human Medicines Regulations 2012 apply to medical devices (see later in this chapter) or veterinary medicines (chapter 16).

**The Human Medicines Regulations 2012**

These Regulations comprise 17 Parts and 35 Schedules. This book focuses on those Parts of greatest relevance to pharmacists and those involved in pharmacy. For full details, readers should consult the actual Regulations,
the accompanying Explanatory Memorandum and the MHRA website. The contents of the Regulations are set below, with where they are predominantly discussed within this book.

Part 1 General provisions: chapter 2
Part 2 Administration: chapter 2
Part 3 Manufacturing and wholesaling: chapters 3 and 10
Part 4 Requirement for authorisation: chapter 3
Part 5 Marketing authorisations: chapter 3
Part 6 Certification of homoeopathic medicinal products: chapter 11
Part 7 Traditional herbal registrations: chapter 12
Part 8 Article 126a Authorisations: chapter 3
Part 9 Borderline products: chapter 3
Part 10 Exceptions to requirement for marketing authorisation, etc.: chapter 3
Part 11 Pharmacovigilance: chapters 2 and 3
Part 12 Dealings with medicinal products: chapters 6, 7, 8 and 9
Part 13 Packaging and leaflets: chapter 14
Part 14 Advertising: chapter 4
Part 15 British Pharmacopoeia: chapter 15
Part 16 Enforcement: chapter 2
Part 17 Miscellaneous: chapter 2

In addition, chapter 5 covers the provisions of the Medicines Act 1968 on pharmacies, chapter 13 provisions in the Act for protection of the purchaser and chapter 16 covers the legislation on veterinary medicines.

**Part 1 General provisions**

**Definition of medicinal product**

The Regulations do not use the term ‘medicine’ but ‘medicinal product’, which is defined (HMRs Part 1, Reg.2) as:

- any substance or combination of substances presented as having properties of preventing or treating disease in human beings; or
- any substance or combination of substances that may be used by or administered to human beings with a view to:
  - restoring, correcting or modifying a physiological function by exerting a pharmacological, immunological or metabolic action, or
  - making a medical diagnosis.

Whole human blood or any human blood components are specifically excluded from the above definition.

The above definition is transposed from Directive 2001/83/EC, as amended. The European Court of Justice (ECJ) has confirmed that falling
under either (a) or (b) above is sufficient to classify a product as a medicinal product,\textsuperscript{5} ruling that 'Directive 65/65 (now Directive 2001/83) provides two definitions of the term \textit{medicinal product}: one relating to presentation, the other to function. A product is medicinal if it falls within either of those definitions.' Directive 2004/27/EC adds a new provision to Article 2 of Directive 2001/83/EC as amended, which states, 'In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a product covered by other Community legislation the provisions of this Directive shall apply.'

Taken together, these provisions are intended to ensure that where doubt exists over whether a product (those on the borderline between, for example, medicines and medical devices, medicines and cosmetics, medicines and food supplements, etc.) should be regulated under medicines or other sectoral legislation, the stricter medicines regulatory regime should apply. This is a broader definition than that in the HMRs and can be defined as being a medicinal product (a) by presentation and (b) by function, as outlined by the ECJ, above.

\textbf{Special provisions restricting scope}

Where medicines are assembled in the course of the professional practice of a doctor, dentist, nurse, midwife or herbalist for the treatment of their patients, no manufacturing licences are required (HMRs Part 1, Reg.3). Similarly where medicines are prepared under the supervision of a pharmacist and in accordance with exemptions in the retained section 10 of the 1968 Act (chapter 3), no licences are required (HMRs Part 1, Reg.4).

\textbf{Classification of medicines}

Regulation 5 of the HMRs provides definitions of the three classifications governing the sale or supply of medicines; these are covered in chapter 6 (Pharmacy Medicines), chapter 7 (General Sale Medicines) and chapter 8 (Prescription Only Medicines).

\textbf{Licensing authority and ministers}

The licensing authority is responsible for the grant, renewal, variation, suspension and revocation of licences, authorisations, certificates and registrations under the Human Medicines Regulations 2012 (Reg.6). The \textit{licensing authority} means either or both the Secretary of State for Health (who must enforce or secure the enforcement of the Regulations and relevant EU provisions in England, Wales and Scotland) and the Minister for Health, Social

\textsuperscript{5}Upjohn 1989 C-122/5
Services and Public Safety (who is responsible for enforcement in Northern Ireland; note that Northern Ireland will not be considered further in this chapter). Note that the Regulations apply to the whole of the UK. Generally, any function that is conferred on the licensing authority by the Regulations is to be exercised by the ministers acting jointly, although there are provisions for certain functions to be exercised by either of them acting alone or both of them acting jointly. While the ministers comprise the licensing authority, these licensing functions are carried out by either the MHRA (which is an executive agency of the Department of Health) or the European Medicines Agency (chapter 3). The MHRA is also the licensing authority for all other licences required under the Regulations (e.g. manufacturers, wholesale dealers) and is also the enforcement authority for these matters in the UK.

Advertisements relating to medicinal products

Regulation 7 of the HMRs defines an advertisement as including anything to promote the prescription, supply or use of a medicinal product. Advertising and sales promotion is discussed in chapter 4.

General interpretation

Regulation 8 of the HMRs includes definitions that apply across the whole Regulations except where there are additional lists that refer to a particular Part only (e.g. there is a further list of definitions that apply only to Part 12, concerned with ‘dealings’ with medicinal products; Reg.213). Most have been defined in the relevant chapter but the following used in this chapter should be noted:

Administer means administer to a human being orally, by injection or by introduction into the body in any other way or by external application (whether or not by direct application to the body), either in its existing state or after it has been dissolved or dispersed in, or diluted or mixed with a substance used as a vehicle

Hospital includes a clinic, nursing home or similar institution.

Part 2 Administration

Two advisory bodies are established under the Regulations, namely the Commission on Human Medicines (HMRs Reg.9) and the British Pharmacopoeia Commission (BPC) (HMRs Reg.11). Each advisory body must have at least eight members and may co-opt one or more additional members for the purposes of a meeting. An advisory body, or the advisory bodies
acting jointly, may with the approval of the licensing authority appoint one or more subcommittees, known as expert advisory groups (see below). Each advisory body must give a report to the ministers each year (HMRs Reg.12), at a time specified by the ministers, about the performance of its functions and of those of any expert advisory group appointed by it. The Secretary of State must lay a copy of each report before parliament.

**Commission on Human Medicines**

The Commission on Human Medicines was established in 2005, under section 2 of the Medicines Act. The 2012 Regulations continue to provide for this body (Reg.9), the members and chair of which are appointed by the ministers, who must consult the Scottish ministers before making such appointments.

The Commission on Human Medicines must give advice to either or both of the ministers in relation to certain matters if the minister (or ministers) requests it or the Commission considers it appropriate to give it. Those matters are any relating to the execution of any duty imposed by, or to the exercise of any power conferred by, the Human Medicines Regulations 2012 or the Clinical Trials Regulations, or otherwise relating to medicinal products.

The Commission on Human Medicines must:

a  give advice with respect to the safety, quality and efficacy of medicinal products and promote the collection and investigation of information relating to adverse reactions, for the purposes of enabling such advice to be given; and

b  advise the licensing authority if the licensing authority:

   i  is required under Schedule 11 or the Clinical Trials Regulations, to consult the Commission about any matter arising under those provisions, or

   ii  consults the Commission about any matter arising under those provisions.

**British Pharmacopoeia Commission**

The Medicines Act established the legal status of the BPC and of the *British Pharmacopoeia* (BP) as the UK standard for medicinal products. The 2012 Regulations continue to provide for this body, the members and chair of which are appointed by the ministers, who must consult the Scottish ministers before making such appointments. The BPC must prepare, or cause to be prepared editions of the BP and any other compendia (HMRs Reg.317) and lists of British Approved Names (HMRs Reg.319) (chapter 15).
Expert advisory groups

The licensing authority may direct that either of the above advisory bodies appoint one or more subcommittees (HMRs Part 2, Reg.14), known as expert advisory groups, to assist them in their work. An advisory body may delegate any of its functions other than those of providing advice to the licensing authority in any case where the licensing authority is required to consult the advisory body under Schedule 11 to the Regulations or the Clinical Trials Regulations. An advisory body may, however, arrange for an expert advisory group to provide advice to the advisory body in relation to the performance of those functions. Regulation 14 also stipulates who may be a member of an expert advisory group and further provisions about advisory bodies and expert advisory groups are found in Schedule 2 to the Regulations.

At the time of going to press, the following expert advisory groups have been established:

- Anti-infectives/HIV/Hepatology
- Biologics/Vaccines
- Cardiovascular/Diabetes/Renal/Respiratory/Allergy
- Chemistry, Pharmacy and Standards
- Clinical Trials
- Dermatology/Rheumatology/Gastroenterology/Immunology
- Medicines for Women’s Health
- Neurology/Pain Management/Psychiatry
- Oncology and Haematology
- Paediatric Medicines
- Patient and Public Engagement
- Pharmacovigilance.

Part 11 Pharmacovigilance

Part 11 of the HMRs places general obligations on the licensing authority, with respect to pharmacovigilance, including an obligation to operate and audit a pharmacovigilance system. Further obligations are applied to the holders of marketing authorisations (chapter 3) but for a detailed account of the pharmacovigilance regime, readers are directed to the HMRs themselves and to the relevant section of the MHRA website (see end of chapter).

Regulation 178 states that the licensing authority must:

a. take all appropriate measures to encourage the reporting to it of suspected adverse reactions;

b. facilitate reporting through the provision of alternative reporting formats in addition to web-based formats;
c take all appropriate measures to obtain accurate and verifiable data for the scientific evaluation of suspected adverse reaction reports;
d ensure that the public is given important information on pharmacovigilance concerns relating to the use of a medicinal product in a timely manner, through publication on the UK web portal, and through other means of publicly available information as necessary; and
e ensure that all appropriate measures are taken to identify any biological medicinal product (including name and batch number) prescribed, dispensed or sold in the UK which is the subject of a suspected adverse reaction report through the methods for collecting data and, where necessary, the follow up of suspected adverse reaction reports.

Part 16: Enforcement

Part 16 of the HMRs covers enforcement. The primary duty of enforcing the Regulations in England, Wales and Scotland rests with the Secretary of State (HMRs Reg.323). There are provisions for ministers to delegate many of their functions to other authorities, but licensing requirements and those provisions which affect hospitals (except so much of the hospital as is a registered pharmacy) or the premises of a doctor’s or dentist’s practice are solely the responsibility of the ministers. In England, Wales and Scotland, arrangements can be made or directions given whereby local drugs authorities and/or the GPhC can have certain duties or exercise certain powers concurrently with the ministers. In Scotland, these enforcement authorities cannot themselves institute proceedings. Under Reg.323 (2), the Secretary of State may delegate (and has delegated) the duty of enforcement in connection with pharmacies and the retail distribution of medicines to the GPhC (chapters 22, 23 and 24). Other enforcement duties may be given to the GPhC and to local authorities (drugs authorities) as the appropriate ministers may decide. In addition, Part IV of the Medicines Act 1968 (Pharmacies) is retained and under that legislation, the GPhC is responsible for the maintenance of the Register of Pharmacy Premises (chapter 5) and for disciplinary control over bodies corporate and representatives of pharmacists carrying on retail pharmacy businesses (chapter 24).

The GPhC, concurrently with the minister, is also required to enforce the provisions relating to sale and supply of medicines not subject to general sale (HMRs Reg.220) and sale or supply of a Prescription Only Medicine (POM; Reg.214). The provisions relating to sale or supply of medicinal products subject to general sale (Reg.221) and sale of medicinal products from automatic machines (Reg.222) are enforced, concurrently with the minister, by the GPhC in relation to premises that are registered pharmacies and, in each area for which there is a drugs authority (see below), by that drugs authority in relation to premises that are not registered pharmacies.
Here, *premises* includes any place and a ship, aircraft, hovercraft or vehicle (Reg.323(11)).

The Secretary of State may make arrangements for either or both of the GPhC or, in respect of each area for which there is a drugs authority, the drugs authority for the area, concurrently with the Secretary of State, to enforce the following provisions:

1. compliance with standards specified in certain publications (Reg.251);
2. offences relating to dealings with medicinal products: compliance with standards specified in certain publications (Reg.255(1)(e));
3. packaging and leaflets (HMRs Part 13); and
4. requirements relating to advertising (HMRs Part 14)

Arrangements made with the GPhC in relation to HMRs Part 14, chapter 2 are to be limited to the enforcement of those provisions in respect of:

1. advertisements displayed or representations made on or in any premises where medicinal products are sold by retail or supplied in circumstances corresponding to retail sale;
2. advertisements displayed on any website associated with such premises; and
3. advertisements displayed on, or in close proximity to, a vending machine in which medicinal products are offered or exposed for sale.

Drugs authority (HMRs Reg.323 (10)) means:

a. in England:
   i. in relation to a non-metropolitan county, metropolitan district or London borough, the council of that county, district or borough, and
   ii. in relation to the City of London (including the Inner Temple and the Middle Temple), the Common Council of the City of London;

b. in Wales, the council of a county or county borough; and

c. in Scotland, a council constituted in relation to a local government area under section 2 of the Local Government etc. (Scotland) Act 1994.

Under the Act, the GPhC is also required to enforce the provisions relating to:

1. prohibition of sale or supply, or importation, of medicinal products of specified description (s.62) (chapters 13 and 24)
2. sale and supply and offer of sale or supply of adulterated medicinal products (s.63)
3. sale of medicinal products not of the nature or quality demanded (s.64)
4. annual return of premises to the Registrar (s.77)
5. restrictions on use of titles, descriptions and emblems (s.78)
6 regulations imposing further restrictions on titles (s.79(2))
7 regulations relating to requirements for containers (s.87(2))
8 regulations relating to distinctive colours, shapes and marking of medicinal products (s.88(3)).

**Inspection, sampling and seizure**

A right of entry, and a right to inspect, take samples and seize goods and documents are given (HMRs Reg.325 and Reg.327) to an inspector in order to ascertain whether there has been a contravention of the Regulations. Inspector means a person authorised in writing by an enforcement authority for the purposes of Part 16 (enforcement) of the Human Medicines Regulations 2012 (HMRs Reg.8).

An inspector, having produced his/her identification if requested to do so, is empowered:

1 at any reasonable time, to enter premises (which includes any place and a ship, aircraft, hovercraft or vehicle) in order to determine whether there has been a contravention of any part of the Regulations which the enforcement authority is required or empowered to enforce.

2 to inspect any of the following to determine whether there has been a contravention of any provision of the Regulations which the enforcement authority must or may enforce:
   a a substance or article appearing to the inspector to be a medicinal product;
   b an article appearing to the inspector to be a container or package used or intended to be used to contain a medicinal product, or a label or leaflet used or intended to be used in connection with a medicinal product;
   c plant or equipment, including computer equipment, appearing to the inspector to be used or intended to be used in connection with the manufacture, assembly, importation, sale, supply or advertising of, or wholesale dealing in, medicinal products;
   d any process of manufacture or assembly of medicinal products;
   e the way in which medicinal products, or the materials used in the manufacture of medicinal products, are tested at any stage in the process of manufacture or assembly;
   f information and documents (including any that are stored electronically) relating to the manufacture, assembly, importation, sale, supply or advertising of, or wholesale dealing in, medicinal products; or
   g information and documents (including any that are stored electronically) relating to the safety of medicinal products, including information and documents relating to compliance with specified parts of the Regulations;
to take or purchase a sample of a substance or article which appears to the inspector to be a medicinal product which is, or is intended to be, sold or supplied or a substance or article used, or intended to be used, in the manufacture of a medicinal product;

4 to require a person carrying on a business which consists of or includes the manufacture, assembly, importation, sale, supply or advertising of, or wholesale dealing in, medicinal products, or a person employed in connection with such a business, to produce information or documents relating to the business which are in the person’s possession or under the person’s control;

5 to take copies of information or documents mentioned, above;

6 to seize and retain a substance or article appearing to the inspector to be a medicinal product if the inspector reasonably believes that an offence under the Regulations is being or has been committed in relation to, or by means of, that substance or article;

7 to seize and retain any document (including any that are stored electronically) or anything inspected, or discovered in the course of an inspection, if the inspector reasonably believes that it may be required as evidence in proceedings; and

8 to require a person who has the authority to do so to open a container, package or vending machine or to allow the inspector to open a container, package or vending machine, for the purpose of enabling the inspector to seize a substance, article, document or other thing, as outlined above.

Where an inspector seizes a substance, article, document or other thing, s/he must, where practicable, inform the person, if any, from whom it was seized, and the occupier of the premises from which it was seized. If the seizure is from a vending machine, s/he must inform the person whose name and address are stated on the machine to be those of the machine’s owner or, if no name and address are stated, the occupier of the premises on which the machine stands or to which it is affixed.

Twenty-four hours’ notice must be given to the occupier if it is intended to enter any premises used only as a private dwelling. In cases where admission is refused, or such refusal is anticipated and notice of the intention to apply for a warrant has been given to the occupier, or where a request for admission, or the giving of notice, would defeat the object of the entry or where the case is one of urgency or the premises are unoccupied or the occupier is temporarily absent, a justice of the peace may issue a warrant authorising an inspector to enter premises, by force if necessary (Reg.326). Regulation 326 goes into further detail regarding who may issue a warrant and its period of validity.

An inspector entering any premises by virtue of a right of entry (Reg.325) or of a warrant under Regulation 326 may be accompanied by such persons, and take such equipment, as the inspector thinks appropriate. Where an
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inspector enters premises in pursuance of a warrant under Regulation 326, the inspector must, if the property is unoccupied or the occupier is temporarily absent, leave the premises as effectively secured against trespass as they were before the inspector entered.

It is an offence either to intentionally obstruct an inspector or to fail to comply with a requirement relating to inspection, sampling or seizure properly made by him or her. It is also an offence, without reasonable cause, to fail to give an inspector any other assistance or information which s/he may reasonably require in order to perform a function under the Regulations or to provide false information in relation to any such requirement (Reg.334). The Regulation goes on to say that ‘Nothing in this regulation is to be read as requiring a person to answer a question or to give information if doing so might incriminate that person or the spouse or civil partner of that person’ (HMRs Reg.334(8)). However, the Pharmacy Order 2010 Article 49 makes it clear that failure on the part of pharmacists or pharmacy technicians to supply information or produce any document required for a fitness to practise investigation may lead to a court order to comply (chapter 24).

An inspector who has exercised a right of entry and discloses to any other person, except in the performance of his/her duty, information about any manufacturing process or trade secret obtained by him/her in the premises commits an offence. It is similarly an offence for any person to disclose any information obtained by him/her in pursuance of the Regulations (Reg.332). An exception to this is if the inspector is or is acting on behalf of a public authority for the purposes of the Freedom of Information Act 2000.

Sampling

A detailed procedure is set out in Schedule 31 of the HMRs for dealing with samples taken by a sampling officer (i.e. a person authorised by an enforcement authority). A sample must be divided into three parts, two being retained by the sampling officer and the third given to the seller in the manner prescribed in the Schedule, according to the circumstances. One of the parts retained by the sampling officer may be submitted for analysis to a medicines control laboratory or to a laboratory available for the purpose in accordance with any arrangements made by the enforcing authority in question.

The laboratory to which a sample is submitted must analyse or examine the sample as soon as practicable and must issue and send to the sampling officer a certificate specifying the result of the analysis or examination. Such a certificate is to be sufficient evidence of the facts stated in the document in proceedings for an offence under the Regulations, unless another party to proceedings requires that the person who issued the certificate be called as a witness. In proceedings in Scotland, if the person who issued the certificate
is called as a witness, that person’s evidence is to be sufficient evidence of the facts stated in the certificate.

The second part of the sample retained by the sampling officer must be produced as evidence and, if required by either party, must be submitted for analysis to the government chemist or be sent for other examination to a laboratory specified by the court.

A sampling officer must pay the value of a sample if it is demanded by the person from whom it is taken; there is provision for arbitration about the value in case of a dispute. The taking of a sample by a sampling officer has effect as though it were a sale of a medicinal product and the provisions of section 64 of the Act relating to the protection of purchasers apply (chapter 13). Any person, other than an inspector or person authorised by an enforcement authority, who has purchased a medicinal product may submit a sample of it for analysis to the public analyst for the area where it was purchased, subject to the analyst’s right to demand payment of the prescribed fee in advance. The public analyst must analyse the sample as soon as is practicable and issue a certificate in the form prescribed (HMRs Reg.330).

Part 17 Legal proceedings

Where a contravention is by reason of the act or omission of another person, that other person may be charged and convicted whether or not proceedings are taken against the person committing the contravention. A person charged with an offence who proves to the satisfaction of the court (a) that s/he exercised all due diligence to prevent the contravention and (b) that the contravention was due to the act or omission another person shall, subject to certain procedural requirements, be acquitted of the offence (HMRs Reg.335).

When an offence is committed by a body corporate, any director, secretary or other similar officer of the body corporate may be proceeded against, as well as the body corporate, if it is proved that the offence was committed with his/her consent or connivance, or was attributable to his/her neglect (Reg.338). Section 124 of the Medicines Act specifically provides that the superintendent pharmacist of a retail pharmacy business (whether or not a member of the board), and any pharmacist manager or assistant acting under his/her direction, shall be regarded as officers for this purpose. Medicinal products proved to have been found on a vehicle from which those goods are sold are presumed to have been offered for sale unless the contrary is proved (HMRs Reg.340). This presumption applies when the offences concern the offering for sale of a medicinal product contrary to the restriction on retail sales (under HMRs Regs.220 and 221). There is also a presumption in respect of the possession of medicinal products (or leaflets referring to them) on premises at which the person charged carries on a business including the
supply of those goods. When the offence concerns packaging and package leaflets (Regs.268 and 269) or requirements relating to child safety (Reg.276), a person is presumed, unless the contrary is proved, to have had medicinal products in his/her possession for the purpose of sale or supply.

Warranty can be pleaded (HMRs Reg.336) as a defence to a charge of contravening Regulations 251 (compliance with standards specified in certain publications), 268 and 269 (offences relating to packaging and package leaflets), 273 (child-resistant containers for regulated medicinal products) and 275 (colouring of aspirin and paracetamol products for children).

Subject to certain formalities, a defendant can rely on warranty if s/he proves that:

a s/he purchased the substance or article in the UK as one which could lawfully be sold, supplied or offered for sale or supply or which could be lawfully sold, supplied or offered for sale or supply under the name or description or for the purpose under or for which it was sold;

b the relevant substance or article was sold with a written warranty certifying a matter specified in paragraph (a), and that if the warranty were true the alleged offence would not have been committed;

c at the time of the commission of the alleged offence the defendant had no reason to believe that the matter certified in the warranty was otherwise; and

d at the time of the commission of the alleged offence the relevant substance or article was in the same state as when the defendant purchased it.

A defendant who is an employee of the person who purchased the substance or article under warranty can rely on the same defence as his/her employer, and a name or description entered in an invoice is deemed to be written warranty that the article described can be sold under that description.

It is an offence for a person to intentionally or recklessly give a purchaser a false warranty or to intentionally to apply (a) a warranty or (b) a certificate of analysis (see above) given in relation to one substance or article to a different substance or article (Reg.337). The validity of licences and licensing decisions is considered under licensing (chapter 3), and certificates issued by the Registrar relating to the premises are dealt with under pharmacies (chapter 4).

Medical devices

The Medical Devices Regulations 2002\(^6\) made under consumer protection legislation implement the EC Medical Devices Directives into UK law. They cover such items as intrauterine devices and diaphragms, dental fillings,
contact lens care products, non-medicated dressings, sutures and ligatures. There are currently four sets of Medical Device Regulations implementing all of the Medical Devices Directives and amendments to date.

The Medical Devices Regulations 2002 define a medical device as any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnosis or therapeutic purposes or both and necessary for its proper application, which:

a is intended by the manufacturer to be used for human beings for the purpose of:
   i diagnosis, prevention, monitoring, treatment or alleviation of disease,
   ii diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
   iii investigation, replacement or modification of the anatomy or of a physiological process, or
   iv control of conception; and

b does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means, and includes devices intended to administer a medicinal product or which incorporate as an integral part a substance which, if used separately, would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device.

The 2002 Regulations have been amended by Regulations in 2003 which cover, amongst other things, the re-classification of breast implants, in 2007 (which covers the re-classification of total hip, knee and shoulder joints) and in 2008 and in 2012 to meet EU obligations.

Conformity: CE marking

The Regulations place obligations on manufacturers to ensure that their devices are safe and fit for their intended purpose before they are CE marked and placed on the market in any EC Member State. The MHRA administers and enforces the legislation. CE marking is a mandatory conformity mark for products placed on the market in the European Economic Area (EEA). The letters CE are the abbreviation of the French phrase conformité Européene, which literally means European conformity. The CE marking on a product indicates that the manufacturer is satisfied that the product conforms to

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7 The Medical Devices (Amendment) Regulations SI 2003 No. 697
8 The Medical Devices (Amendment) Regulations SI 2007 No. 400
9 The Medical Devices (Amendment) Regulations SI 2008 No. 2936
10 The Medical Devices (Amendment) Regulations SI 2012 No. 1426

Sample chapter from the 10th edition of Dale and Appelbe’s Pharmacy and Medicines Law
all relevant essential requirements in the Directives and that it is fit for its intended purpose (Directive 93/68/EEC). In general, a medical device cannot be marketed in Europe without carrying a CE marking. A CE marking is applied by the manufacturer and means that the device meets the relevant regulatory requirements and, when used as intended, works properly and is acceptably safe.

For all but the very lowest risk devices, this must be verified by an independent certification body, called a Notified Body, before the CE marking can be affixed. The MHRA is responsible for appointing UK Notified Bodies and regularly audits them to ensure that they perform to the required standards. Custom-made devices, devices undergoing a clinical investigation and in vitro diagnostic medical devices for performance evaluation are exempted from the requirement for CE marking. Unless there are grounds for suspecting that a device may pose a risk to public health, Member States must not ‘create any obstacles to the placing on the market or the putting into service of any medical devices as defined under the Directive bearing a legitimate CE marking’ (Directive 98/79/EC). This means that a CE-marked device may have access to the whole of the Community market and manufacturers are not required to comply with any national schemes when exporting their devices to other countries in the EU.

Summary

- European Directives and Regulations together with the Medicines Act 1968 and the Human Medicines Regulations 2012 regulate the manufacture, distribution and importation of medicines for human use.
- The advisory structure for the ministers is principally the Commission on Human Medicines, which may delegate some of its functions to an expert advisory group.
- The definition of a medicinal product is set out in the Human Medicines Regulations 2012.
- The enforcement of parts of the Regulations falls upon the MHRA and the GPhC; some elements are enforced by ‘drugs authorities’.
- The powers of the inspectors are laid down and stringent conditions relate to the taking of samples within a sampling procedure.
- Those liable to commit offences under the Regulations are listed together with any defences that can be raised.
- Medical devices are controlled under consumer protection legislation but are still administered by the MHRA; a CE mark means that a device is safe and fit for its intended purpose.
Further reading


Websites