GUIDANCE TO THE NHS ON THE LICENSING REQUIREMENTS OF THE MEDICINES ACT 1968

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FOREWORD

This booklet provides guidance and advice for the National Health Service (NHS) on the application of the licensing provisions in the Medicines Act 1968 and its secondary legislation in particular those provisions governing the manufacture, preparation, and distribution of medicinal products. It replaces the guidance issued by the Medicines Control Agency (MCA) on 12 September 1990 entitled "Guidance and Advice to Health Authorities and Self Governing Trusts on Licences and Registrations for the Manufacture, Sale and Supply of Medicines" and has been written after consultation with pharmacists in the NHS and others with an interest in this subject. The MCA is grateful for the assistance which it has received. Further guidance is available from the MCA in its series of Medicines Act Leaflets available on request from Room 1207 Market Towers, 1 Nine Elms Lane, London SW8 5NQ.

Every effort has been made to ensure that the material which follows is accurate and complete but this guidance must not be regarded as a definitive statement of the law. The MCA would find it helpful if any queries arising from the NHS concerning this guidance could initially be addressed to the appropriate Regional Pharmaceutical Officer (RPHO) or the respective Chief Pharmaceutical Officer for Scotland, Wales or Northern Ireland[1].

[1]The guidance should be taken to apply to Northern Ireland, Scotland and Wales with appropriate allowances made within the text for differing organisational arrangements/nomenclatures that may apply.

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1. INTRODUCTION

1.1 On 1 April 1991, crown immunity was withdrawn from the NHS by virtue of the NHS and Community Care Act 1990. The provisions of the Medicines Act 1968 then fully applied to any NHS Authority or officer who carried out specific activities relating to medicinal products. That is the manufacture or preparation of such products and their sale, supply, administration or use.

The Medicines Act

1.2 The Medicines Act 1968 ("the Act") established several statutory bodies and required these to discharge specific functions. Most of these bodies currently operate under the umbrella of the MCA. One such body is the Licensing Authority (LA), defined in Section 6 of the Act as a Minister or a group of Ministers. In practice, Ministers delegate the day-to-day work of the LA to officers of the MCA.

1.3 Activities are subject to the Act only if undertaken "in the course of a business". The Act defines "business" so as to include a professional practice and any activity carried on by a body of persons whether corporate or unincorporate. Section 131(5) of the Act stipulates that the provision of services in the NHS shall be treated as the "carrying on of a business". Activities subject to the Act can only be carried out if the appropriate licences or registration required by the Act are held or if one of the exemptions specified in the Act applies.

The LA has powers to enforce the Act, if necessary through the Courts, including the withdrawal of licences, if the conditions upon which these were granted are not met.

1.4 The LA also has to ensure that exemptions are properly applied, that guidance and advice is available and that the Act continues to fulfil the intentions which led to its promulgation. In this latter context, officers of the MCA advise Ministers and may suggest consideration of further primary or secondary legislation. The policy of the LA is to consult widely before issuing guidance, interpretations or rulings and to provide a framework within which persons can carry out activities efficiently and effectively. Interpretations and rulings issued by the LA should be followed but are open to challenge through the Courts.

Crown Immunity

1.5 Under the British Constitution, the Monarch and her servants are held to be immune from prosecution. Section 133(3) of the Act provides that the Act should not bind the Crown. The NHS is considered to be an arm of the Crown, therefore before 1 April 1991 the NHS could choose whether or not to comply with the Act. The effect of the change on 1 April 1991 was to remove the NHS from the scope of section 133(3), thereby abolishing Crown Immunity insofar as the NHS was concerned for the purposes of the Act.

1.6 Before 1 April 1991, the NHS in general had chosen not to apply for licences but it had undertaken to carry out licensable activities as if licences had been granted and to conduct its other relevant activities in accordance with the Act. Therefore the withdrawal of crown immunity from the NHS should only have had a marginal impact on NHS working practices. The significant changes being that licences would be required for licensable activities and an understanding would be needed about which activities were licensable and which were covered by one of the Act's exemptions.

1.7 In order that licences could be held, it was necessary to decide which units within the NHS could apply for licences. An applicant for a licence has to demonstrate that he is carrying on a business, that he has effective control over the activities for which he requires a licence, and that he or his business is recognised in law. After consultations with the NHS, the LA decided that applications for licences would be accepted from Self Governing Trusts (SGTs), District Health Authorities (DHAs) and other similar "corporate bodies" within the NHS. A corporate body is a collective mass of persons legally empowered to act as a person. DHAs and SGTs are such corporate bodies, each is recognised in law and has the power and accountability with which to discharge the responsibilities of a licence holder.

Liability

1.8 There is a corporate and personal liability for activities concerning medicinal products which can be the subject of civil action or criminal prosecution. The LA is responsible for enforcing the licensing provisions of the Act. The Royal Pharmaceutical Society (RPSGB) has similar responsibilities concerning the provisions of the Act which relate to retail sale and supply. Civil proceedings can be brought by other parties and the Act does not preclude other parties from bringing criminal prosecutions.

1.9 A corporate body may be held to be in default of its liabilities if it has either failed to take action or to have acted erroneously. For instance, failure to hold a licence for the activity of manufacturing medicinal products is a criminal offence, this may also be a factor in any civil action for negligence. In addition, an individual may be in default of his personal liabilities if he has acted negligently or contrary to the instructions of his employer.

1.10 A more detailed consideration of the subject of liability is outside the remit of this guidance. The issue can be complex and it would be appropriate for the NHS to seek further advice from its own legal advisers. In broad terms, the LA advises that:

(i) appropriate licences are applied for and held,

(ii) when activities are carried out under the exemptions authorised by the Act, the necessary conditions are known and complied with,

(iii) written policies and procedures exist when necessary at appropriate levels so that the requirements of the Act can be understood and met,

(iv) officers whose activities bring them within the remit of the Act understand their responsibilities.

2. LICENCES, REGISTRATIONS AND EXEMPTIONS

2.1 The Act is primarily about consumer protection. It seeks to ensure that a person using a medicinal product produced in accordance with the Act can make reasonable assumptions about the safety, quality and efficacy of that product. One of the principal ways the Act affords consumer protection is by a regulatory scheme of licences, registrations, and exemptions therefrom. The Act states what is to be regulated and the means, what is exempt and the conditions governing exemption.

2.2 In addition to the Act itself there also exists a body of secondary legislation (Statutory Instruments (SI's)). These SIs mainly add the finer details to the provisions of the Act but they may also be used to amend the Act for instance, to incorporate changes to UK legislation arising from Directives issued by the European Economic Community.

Licences and Registrations

2.3 In essence, and much simplified, the regulatory scheme is as follows:

(i) **Product Licence** (PL): issued on application when the Licensing Authority is satisfied regarding the product's inherent safety, quality and efficacy for the indicated purpose or purposes. Enables a product to be placed on the market for its licensed use. (Section 7(2) of the Act)

(ii) **Manufacturer's Licence** (ML): issued when the Licensing Authority is satisfied that an applicant can manufacture and/or assemble medicinal products to acceptable standards so as to ensure the safety, quality and efficacy of those products. (Section 8(2) of the Act)

(iii) **Wholesale Dealer's Licence** (WDL): issued when the Licensing Authority is satisfied that an applicant can meet acceptable standards of storage, distribution and stock control so as to preserve the safety, quality and efficacy of the products handled. (Section 8(3) of the Act)

(iv) **the registration of premises where a retail pharmacy business is carried on:** permits retail sale or equivalent supply of POMs and other medicines. (section 52 of the Act). Application for registration is made to the Royal Pharmaceutical Society.

(v) **Exemption for practitioners:** from the otherwise licensable act of procuring sale, supply or manufacture. (Section 9 of the Act)

(vi) **Exemption for pharmacists:** from the requirement to hold either a manufacturer's licence or a wholesale dealer's licence. (Section 10 of the Act)

(vii) **Exemption for hospitals:** from the registration set out in (iv) above when, in the course of the business of the hospital, products are sold, offered for sale or supplied for the purposes of being administered in accordance with the directions of a doctor or dentist (Section 55 of the Act).

(viii) **Exemption from the need to hold a product licence where supply is to be made in specified circumstances:** permits a manufacturer to manufacture and/or assemble medicinal products to the order of a practitioner. (SI 1971/1450)

Definitions

2.4 Many of the terms used in this Guidance have a precise meaning which have either been assigned to them by Section 132(1) of the Act (sub paragraphs (ii) to (ix) inclusive) or which have been interpreted by the LA so as to accurately reflect other legislation. Officers may find the following list helpful when checking to ensure that their interpretation of a term or phrase is consistent with that of the LA.

(i) **Corporate body:** a collective mass of persons empowered to act as a person eg a DHA, SGT.

(ii) **Manufacture:** "manufacture", in relation to a medicinal product, includes any process carried out in the course of making the product,

but does not include dissolving or dispersing the product in, or diluting or mixing it with, some other substance used as a vehicle for the purpose of administering it and does not include the incorporation of the product in any animal feeding stuff.

(iii) **Assemble:** "assemble", in relation to a medicinal product, means enclosing the product (with or without other medicinal products of the same description) in a container which is labelled before the product is sold or supplied or, where the product (with or without other medicinal products of the same description) is already enclosed in the container in which it is to be sold or supplied, labelling the container before the product is sold or supplied in it, and "assembly" has a corresponding meaning.

(iv) **Container:** "container", in relation to a medicinal product, means the bottle, jar, box, packet or other receptacle which contains or is to contain it, not being a capsule, cachet or other article in which the product is or is to be administered, and where any such receptacle is or is to be contained in another such receptacle, includes the former but does not include the latter receptacle.

(v) **Labelling:** "labelling", in relation to a container or package of medicinal products, means affixing to or otherwise displaying on it a notice describing or otherwise relating to the contents, and "label" has a corresponding meaning.

(vi) **Leaflet:** "leaflet" includes any written information.

(vii) **Package:** "package", in relation to any medicinal products, means any box, packet or other article in which one or more containers of the products are or are to be enclosed, and, where any such box, packet or other article is or is to be itself enclosed in one or more other boxes, packets or other articles, includes each of the boxes, packets or articles in question.

(viii) **Hospital:** "hospital" includes a clinic, nursing home or similar institution.

(ix) **Practitioner:** "practitioner" (except where that word occurs as part of the expression "veterinary practitioner") means a doctor, dentist, veterinary surgeon or veterinary practitioner.

(x) **Sale:** the exchange of a commodity for money or other equivalent (including accounting or budget transfers). The Act defines separately the acts of wholesale or retail sale.

(xi) **Wholesale:** sale to a person who buys (a medicinal product) for the purpose of selling or supplying it or administering it or causing it to be administered in the course of a business carried on by that person.

(xii) **Retail:** sale or supply of a medicinal product to a person who buys it otherwise than for one of the purposes specified for wholesale.

(xiii) **Dispensing:** the activity of supplying the product in its appropriate form to the patient pursuant to a doctor's prescription. This activity includes issue by the pharmacist to a person authorised to administer the product or cause it to be administered to the patient. This is a narrower definition than is sometimes used in the NHS, activities taking place prior to the act of supply are in this guidance defined as "preparation", "assembly" or "manufacture".

Applying for Licences

2.5 Most licence holders in the NHS will either be District Health Authorities (DHAs), or Self-Governing Trusts (SGTs). These are corporate bodies having effective control over licensable activities. A Regional Health Authority (RHA) is also a body corporate. Some RHAs centralise licensable activities within their region under the direct control of the RHA. In these regions it may be appropriate for the RHA to be the licence holder, naming as "sites" on its licence those locations where licensable activities are carried out. However, the LA will not accept that an RHA can be the licence holder if the licensable activity is carried out by a SGT. The LA considers that the degree of

independence accompanying the award of SGT status is such that a SGT must hold its own licences for its own activities.

2.6 Care is needed when deciding who should make applications for licences. For instance, a NHS unit may be manufacturing medicinal products within the premises of a SGT but officers in the unit may be employees of the RHA. In these circumstances it may be appropriate for the RHA to be the holder of the manufacturer's licence. The LA will always advise on these situations when asked.

2.7 Applications for manufacturer's and wholesale dealer's licences should be made to: The Medicines Control Agency, Room 1809, Market Towers, 1 Nine Elms Lane, London SW8 5NQ. Applications for product licences should be made to Room 1118 at the same address.

Applying for Registrations

2.8 A hospital pharmacy may wish to register its premises as a place where a retail pharmacy business is carried on. This will enable it to sell pharmacy (P) medicines to a person using them "otherwise than in accordance with the direction of a doctor or dentist" and supply all classes of medicines by retail (see para 6.10 et seq). Applications for such registration should be made to the Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London SE1 7JN.

Exemptions

2.9 The LA does not "authorise" exemptions in the same way as it authorises licences. For most of the exemptions likely to be of concern to the NHS, it is the responsibility of the corporate body to establish that an exemption covers the activity under consideration and that, therefore, licence or registration is not needed. The LA is available for advice if required. The exceptions to this general position are:

(i) the exemptions afforded by SI 1971/1450 from the need to hold or be named on a product licence in order to manufacture medicinal products ("specials") only apply if an appropriate manufacturer's licence is held (known colloquially as a ML "specials") authorising manufacture of those products;

(ii) exemptions in relation to clinical trials;

(iii) exemptions allowing the importation of medicinal products without a product licence (SI 1984/673) require prior application to the LA.

2.10 Sections 15 and 57 of the Act give powers to Ministers to repeal, modify, extend or clarify the exemption provisions. Officers of the MCA are required to keep under review the operation of these provisions. In particular, the LA needs to ensure that the uses made of exemptions do not run contrary to the purpose of the Act. The LA will, therefore, periodically review the uses made of exemptions within the NHS, initially by consultation with RPHOs and CPHOs.

3. MEDICINAL PRODUCTS

Classification

3.1 What constitutes a medicinal product is defined in section 130 of the Act. There are various ways of classifying products which fall within this broad definition. One is according to sale status; be it "prescription only" (POMs), "pharmacy only" (P) and "General Sale List" (GSL), a familiar classification. Another classification relevant to the Medicines Act is:

(i) **Licensed medicinal products:** products in respect of which a PL has been granted and which have been manufactured and assembled by the holder of a ML.

(ii) **"Specials":** medicinal products in respect of which a PL is not in existence but which have been made by the holder of a special manufacturer's licence to the order of a practitioner for administration to a particular patient.

(iii) **Prepared medicines:** medicinal products in respect of which a PL is not in existence but which have been prepared in a registered pharmacy, hospital or health centre by or under the supervision of a pharmacist in accordance with a prescription given by a practitioner or in anticipation of such a prescription and with a view to dispensing the product.

Licensed Medicinal Products

3.2 Such medicinal products must have been made in accordance with the terms of the PL. This means that, amongst other things, the production, packaging, labelling and testing must have been carried out as required by the PL and on the sites named on the PL. These processes can only be carried out by persons holding a manufacturer's licence (ML) or in the case of packaging and labelling only, a manufacturer's (assembly only) licence (unless the site named is not in the UK). The ML holder must either hold the PL or be named on the PL by the PL holder as an authorised manufacturer and/or assembler.

3.3 Once released by the manufacturer a licensed medicinal product only remains such if the packaging and labelling in which the product is enclosed remains intact and is not changed until the point at which the medicine is administered ("original pack dispensing"). If the product's packaging and labelling is changed before being administered in any way the effect in law is to "de-licence" the product. It is permissible to overlabel outer packs or to change outer packs without causing the de-licensing of the product, eg a dispensing label can be put on an outer pack without infringing the PL.

"Specials"

3.4 These products are not subject to PLs but they will have been manufactured by the holder of a manufacturer's ("specials") licence. It may be the case that such products are similar or identical to a licensed product but, in law, if the manufacturer is not named on the PL, (or is not the holder of the PL) or if the formulation, packaging, labelling and so on is not in accordance with the PL, then the product being supplied is not a licensed product.

3.5 The manufacture, supply and use of "specials" is regulated and the conditions mentioned at 3.1(ii) must apply. Practitioners who order "specials" should be aware that they have a responsibility for the safety and efficacy of that product for their particular patient. Pharmacists who procure and sell on or supply "specials" have a responsibility for the inherent quality and safety of the product being sold or supplied.

Prepared Medicinal Products

3.6 These are products which are prepared within the hospital pharmacy either for dispensing or in anticipation of dispensing in accordance with a prescription given by a practitioner. Prepared products have a similar status to that of "specials". The preparing or supervising pharmacist has a professional responsibility for the inherent quality and safety of the product he supplies.

3.7 The NHS therefore has some options to consider when deciding how to meet internal demands for medicines. If "specials" or "prepared" medicinal products are used, all those participating in prescribing, ordering, preparing, assembling, dispensing and

administering such products must be aware of the status of the products and the concomitant responsibilities they have.

4. MANUFACTURING AND PREPARATION OF MEDICINAL PRODUCTS

4.1 The Act establishes two ways by which medicinal products can be made. Either they can be manufactured under licences issued by the Licensing Authority, or they can be prepared under an exemption in the Act "by or under the supervision of a pharmacist".

Manufacture or Preparation?

4.2 Section 132(1) of the Act, defines "manufacture" but not "preparation". In the light of this the guidelines set out in 4.3 et seq were drawn up by a joint working party from the MCA and RPHOs. If problems are encountered in working within the guidelines or if clarification is needed it would be helpful if the matters were first raised with the appropriate CPHO or RPHO. If necessary the working party can review its guidelines and/or consult more widely.

4.3 Those involved in judging whether a particular activity is manufacture or preparation should have regard to the following:

(i) The location in which the process is carried out (i.e. a dedicated production unit or incorporated within other activities in a hospital pharmacy).

(ii) The nature of the activities (ie either batch production similar to small or large-scale commercial manufacturing or a multitude of small tasks over a wide range of medicines).

(iii) The quantities being made (see 4.5 below).

4.4 A dedicated production unit engaged in batch production on a commercial scale is likely to require a manufacturer's licence. The making of a variety of products on a small scale in the hospital pharmacy is likely to be "preparation" and the use of the exemption in section 10 of the Act should then be considered.

Limits on Pharmaceutical Form

4.5 The exemption conferred by section 10 applies to preparation for named patients provided that the conditions of the exemption are met (see para 3.1(iii) and 4.17 et seq). It

can also apply to preparing stock from which to dispense to named patients in accordance with a prescription provided that the limitations stated in 4.6 and 4.7 are not exceeded. These limits apply solely to preparing medicinal products for stock, preparing for dispensing to named patients is outwith these limits.

4.6 **Limits allowable under "preparation for stock"**

Aseptic "preparation for stock" should be avoided. Wherever possible such products should be manufactured in licensed manufacturing facilities.

If aseptic "preparation" has to take place outside licensed facilities the following conditions should apply:-

(i) The preparation is done by or under the supervision of a pharmacist.

(ii) The preparation uses closed systems.

(iii) Licensed medicinal products are used as ingredients or the ingredients are manufactured in licensed facilities.

(iv) Products will be given an expiry date of no more than 1 week. The shelf life should be supported by stability data.

(v) All activities should be in accordance with defined NHS guidelines.

For all other products the limits set out in 4.7 should be adhered to:-

4.7 **Advisory limits on the maximum batch size prepared for stock**

(i)	Non sterile liquids	20 packs
(ii)	Cream or ointments	20 packs
(iii)	Antiseptics, non-sterile topical liquids	20 packs

(iv)	Capsules, tablets, sachets, powders, suppositories, pessaries, bougies	100 units (eg tablets)
(v)	Ear drops - non sterile	20 packs
(vi)	Terminally sterilised products including eye and ear drops, injections, sterile creams or ointments	10 packs
(vii)	Sterile topical liquids	20 packs
(viii)	Repackaging	25 packs

* A pack is defined as one filled container eg a bottle of tablets or liquid, or a tube of ointment etc.

Frequency

4.8 There should be a limit of one batch per month of items prepared for stock with the exception of aseptically prepared products. Wherever possible, pharmacy departments should co-operate to rationalise products or pack size so as to allow licensed manufacture in preference to preparation for stock. However, very small batches of very short dated products may need to be prepared routinely for stock to cover weekends or bank holidays.

4.9 The limits for preparation for stock have to take account of the batch size, the number of containers in the batch, the annual demand and the shelf life of the product. Although preparation for stock within the above limits is exempted from licensing, an acceptable level of quality assurance is nevertheless still required. Products should be made to contemporary standards of good manufacturing and good dispensing practice. Facilities and procedures should be regularly audited by quality control staff. Unlicensed starting materials used in preparation should be approved for use by quality control staff.

4.10 The expiry date prescribed for a compounded product should be supported by stability data. A validated shelf life should be agreed with Quality Control. Where a shelf

life of 28 days or more is being assigned, consideration should be given to producing these products in a licensed manufacturing unit. For repacked tablets/capsules, the expiry date should be 12 months or the manufacturer's expiry date, whichever is the earlier unless validated stability data is available to justify a longer shelf life.

4.11 Records should be kept of all product compounded, assembled or repackaged under these guidelines. These records should be summarised every 3 months.

Manufacturing

4.12 If the NHS officer concludes that his activity is and will continue to be "manufacturing" he must apply for a manufacturer's licence from the MCA, (see paragraph 2.7). On making application, an inspection will be made by an MCA Inspector and further advice and guidance given on the conditions under which a licence can be granted.

4.13 The officer will also have to decide whether his manufacturing is to be of licensed products or "specials". If it is the former, he will need to be either the PL holder or named on the PL as a manufacturer of the licensed products which he proposes manufacturing.

4.14 If manufacture is to be of "specials" the officer must follow the regulations which govern this type of manufacture. The relevant Statutory Instruments (SIs No 1971/1450 and 1972/1200) require that "certain circumstances" and "specified conditions" must be satisfied in order that manufacture may be legally undertaken. This is particularly relevant if licensed products are to be manufactured in addition to "specials". Action which can legally be taken in respect of the former might, if taken in respect of the latter, be illegal.

4.15 "Certain circumstances": Manufacture of "specials" can only take place in response to a bona-fide unsolicited order from a person authorised in the SIs to place such an order and who intends to use the product in a way which falls within the terms specified in the SIs. Usually this person is a doctor or dentist who wishes to prescribe a particular medicine for a patient or small group of patients with a view to administering the product to such patients. The person ordering the product should therefore declare his professional status to the licence holder and state the purpose for which his order is required.

4.16 "Specified conditions": These in the main relate to advertising and promotional material. The manufacturer can advertise his "specials" service but no advertisement, representation or promotion can be issued relating to an unlicensed medicinal product. Section 92(1) of the Act defines the term "advertisement". It includes advertising by means of catalogue, price list or circular letter. In addition, section 96 of the Act sets out the circumstances in which data sheets can be sent to practitioners, Sub-section (6) of that section defines a data sheet as "a document prepared by or on behalf of the holder of a product licence". It follows that data sheets cannot be issued in respect of medicinal products for which there is no product licence. This includes those products manufactured under a "specials" licence.

Preparation

4.17 If the NHS officer decides that his activities will be "preparation" and therefore exempt from licensing he must consider the requirements he must fulfil in order that the exemption can apply.

4.18 Section 9 of the Act, inter-alia, provides exemptions for practitioners from the otherwise licensable act of procuring the manufacture of a product which he wishes to prescribe. This exemption applies for administration to a particular patient of the practitioner, or when supplying to a person who has care of the patient. Thus section 9 allows the practitioner, without holding a PL himself, to procure some other person to prepare the medicinal product. Such "other person" is not necessarily exempt from the need to hold a manufacturer's licence.

4.19 Section 10 of the Act provides the pharmacist with an exemption from the requirement to hold a ML that otherwise would apply in the circumstances described in 4.18 so as to enable him to meet the practitioner's order. Under section 10 of the Act, the pharmacist is exempt from the need to hold a ML when preparing a medicinal product in accordance with a practitioner's prescription or when similarly packing or labelling medicinal products, including substances supplied to him in bulk.

4.20 The section 10 exemption applies only to activities in a registered retail pharmacy or in a hospital or in a health centre. The exempted activities are limited in

scope. They do not extend to the marketing or general sale by a pharmacist of a product made to his own specification.

4.21 Section 10 also provides an exemption from the requirement to hold an ML, not solely for the activities of the pharmacist but also for those relevant activities done in the course of the business of the hospital or health centre, whoever is carrying them out provided that these are done under the supervision of the pharmacist.

4.22 The expression "under the supervision of a pharmacist" as used in the Act is the same as in section 18(1)(a)(iii) of the Pharmacy and Poisons Act 1933 (which relates to conditions under which a poison may be sold). In the context of the Act, the supervising pharmacist is required to be present at the place where the activity is carried out and in a position to intervene.

4.23 When preparing medicinal products under a section 10 exemption, the pharmacist must act in accordance with a prescription given by a practitioner (unless he is preparing stock - see 4.5 et seq). This does not necessarily mean that the prescription must be to hand. However, the pharmacist must have a means of ensuring that he is acting in accordance with a prescription in order that his activities can be regarded as exempt from licensing and that if called upon to confirm this, he is able to do so by reference to written records ("writing" including "any form of notation whether by hand or by printing, typewriting or similar process": Section 132(1) of the Act). The precise form of records is for the pharmacist (or the NHS) to determine.

5. ASSEMBLY OF A MEDICINAL PRODUCT

5.1 The definition of "assembly" in section 132(1) of the Act is: "enclosing a product (with or without medicinal products of the same description) in a container which is labelled before the product is sold or supplied, or, where the product (with or without medicinal products of the same description) is already enclosed in the container in which it is to be sold or supplied, labelling the container before the product is sold or supplied in it, and "assembly" has a similar meaning". Section 132(1) of the Act also defines a "container" and a "package" (see paragraph 2.4 of this guidance). These activities are often referred to as "breaking bulk, pre-packing, repacking" or "packing down". Care should be taken not to confuse "overlabelling" with assembly as the former is not a licensable activity. It is permissible both to overlabel outer packs or to change outer packs without needing to hold a manufacturer's (assembly) licence.

5.2 Much of what has already been written earlier in this guidance about manufacture and preparation also applies to assembly. The guidelines in part 4 should therefore be followed when reviewing an assembly activity in order to decide whether the activity requires an assembly licence or is able to be carried out by virtue of the section 10 exemption.

5.3 Officers must bear in mind that any assembly activities relating to licensed products have the effect of changing the status of the medicinal products into that of a "special" (3.1(ii) et seq) unless:

(i) the new form of container or packaging or labelling is as specified on the product licence for that medicinal product

and

(ii) the corporate body responsible for the assembly activity is the holder of a manufacturer's (assembly) licence

and

(iii) the site at which the assembly activity is taking place is named on the Product Licence and on the manufacturer's (assembly) licence.

5.4 Officers should also not overlook the fact that the regulations concerning the labelling of the assembled medicinal products apply irrespective of whether or not those products are licensed or "specials". These regulations are to be found in SI 1976/1726 as amended.

6. SALE AND SUPPLY OF MEDICINAL PRODUCTS

6.1 The Act regulates the sale or the supply of medicinal products and makes a distinction between wholesale (section 8 of the Act) and retail sale or equivalent supply otherwise than by sale (section 52 and 53 of the Act). A licence is required to wholesale deal. Medicines (other than GSL) can be sold or supplied by way of retail sale or equivalent supply only from premises registered as a pharmacy (see 2.8) unless a Medicines Act exemption applies. The person supplying such medicine must either be a pharmacist or be acting under the supervision of a pharmacist and in the case of POMs, such sale or supply can only be made in accordance with the directions of a doctor or dentist.

6.2 The Act (sections 9, 10 and 55 and 57) makes provision for exemptions from the requirements set out in 6.1 above whereby sale and supply can take place without a licence or registration[2]. The NHS activity of dispensing is generally covered by one or other of these exemptions. Officers need to ensure that for any particular sale or supply activity (including dispensing) they understand the legal framework within which the activity is taking place and that when necessary the appropriate licence or registration is held.

Emergency Situations

6.3 The LA is always ready to advise those who may be faced with supplying medicinal products in an emergency (such as a life-threatening situation or a national or local emergency) and who are concerned that such supply may not be lawful. The MCA telephone number to ring for such advice is 071-273 0605 or 0607. Advice is given on a case-by-case basis but the LA would not normally seek to enforce the Act in a situation of overriding need. It would be appropriate for the senior pharmacist to consult the LA before acting if possible, or if not as soon after the event as may be practical, and to keep a record of the supply activity.

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[2]there is also a range of exemptions for the retail sale or supply of POM or P medicines by non-pharmacists eg practitioners and midwives. These are not covered by this guidance.

Definitions

6.4 In order to ensure that sale or supply activities are lawful, officers need an understanding of the terminology used to differentiate between wholesale, retail sale or supply, and dispensing. Paragraph 2.4 sets out the appropriate definitions.

6.5 Officers will probably find it is easier to decide first whether the sale or supply activity under consideration is wholesale, or supply in the circumstances described later in para 6.13, or retail sale, or supply equivalent to retail sale. Secondly they will have to decide whether the activity is exempt under the Act from the regulatory requirement that otherwise would ensue.

Wholesale

6.6 An activity will be a wholesale transaction in the following circumstances:

(i) a sale takes place, and

(ii) the transaction is between two corporate bodies and

(iii) the medicinal product is purchased for the purpose of administering it in the course of a business or causing it to be administered in the course of a business or selling or supplying it to another in the course of a business.

6.7 Therefore, the sale of medicinal products from one SGT to another, or from a RHA to a DHA, or a DHA to another DHA etc is prima facie a wholesale transaction. Unless the exemption in section 10 of the Act and described below in 6.8 is applicable, a licence to wholesale should be applied for (see 2.7).

6.8 Under section 10 of the Act the activity described above will be exempt from the requirement to be licensed if the following conditions are met:

(i) the activity takes place in either a registered pharmacy or a hospital or a health centre, and

(ii) it is undertaken by or under the supervision of a pharmacist, and

(iii) in accordance with a prescription or order given by a practitioner, and

(iv) the person receiving the product is authorised to administer the product or cause it to be administered. NB:- Such persons are not allowed to sell or supply the product to anyone else, other than to a person who is authorised to administer under their direction. They must retain custody of the product and either administer it, cause it to be administered or return it to their supplier. For instance, a ward sister may supply her nurses but not another ward.

6.9 The exemption described in 6.8 derives from section 10 of the Act. Provided the conditions are met, a pharmacy or hospital in one corporate body can meet a demand for medicinal products from, for instance, wards hospitals or doctors, in another corporate body without the need to hold a licence to wholesale. This exempted transaction will probably occur most frequently between SGTs or DHAs but it is also possible under these provisions for the exempted transaction to take place with private hospitals, hospices and other similar corporate bodies.

Retail sale or equivalent supply

6.10 Retail sale or equivalent supply with one exception (see 6.13), encompasses all other NHS sale or supply activity provided that the person receiving the product does so for a purpose other than:-

(i) selling or supplying it to another, or

(ii) administering it or causing it to be administered.

in the course of a business carried out by that person.

The most common activity will be the sale or supply of a medicinal product to a patient or a member of the public for self-administration.

6.11 Retail sale or equivalent supply of POM or P medicines can only be carried out by a person lawfully conducting a retail pharmacy business from premises registered as a

pharmacy, or a person specifically exempted by the Act from this requirement[3]. The exemption likely to be used in the NHS is that contained in section 55 of the Act. Provided the following conditions are met this confers an exemption from the requirement to be "lawfully conducting a retail pharmacy ... etc".

(i) the activity takes place in the course of the business of a hospital or health centre and

(ii) the product is sold or supplied for the purpose of being administered in accordance with the directions of a doctor or dentist and

(iii) in the case of POMs; the directions at (ii) are written.

6.12 A hospital or health centre meeting the conditions of 6.11 can therefore sell or supply a medicinal product (dispense), to any patient of any doctor, irrespective of whether that patient is a patient of the hospital making the sale or supply and without the need to meet the pharmacy registration requirements that otherwise would apply. This includes "to take out" (TTO) activity.

Supply within the Corporate Body

6.13 There remains one activity not covered in the earlier paragraphs. That is supply within a corporate body other than by retail sale or equivalent supply, for instance supply from the pharmacy to wards within the same hospital or supply from one hospital pharmacy to a pharmacy or ward in another hospital, both of which belong to the same SGT or DHA.

6.14 This activity is not regarded as licensable by the LA. In practice, this means that the corporate body, usually the DHA or SGT, has the responsibility for the safe custody, control and storage of its medicinal products[4], irrespective of the location or movement of such products within its domain, until the products are either dispensed, sold or supplied under the appropriate regulatory requirements.

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[3]Certain exemptions for practitioners and midwives have already been mentioned in the footnote to paragraph 6.2 and are not the subject of this guidance.

[4]The Duthie Report provides advice on this subject.

Records

6.15 Requirements to keep records are among the conditions which holders of licences and those holding pharmacy "registrations" have to meet in order to hold such licences or registrations. No such provisions apply *per se* to activities which are exempt from regulatory requirements, (these will in the main be dispensing activities).

6.16 The LA recommend that those providing dispensing services should keep adequate records of such transactions in a form which shows that the conditions of exemption are being met. As a matter of good practice, accountability and responsibility should be clear and working practices should not drift from the conditions of the exemption. Pharmacists may also wish to review how they ensure that a person receiving a supply of medicinal products "to administer or cause to be administered" (6.8(iv)) understands the conditions and is not departing from them (for instance by supplying to other wards and units).

6.17 The Act includes provision for Ministers to extend or modify the exemptions. Officers of the MCA have to keep under review the application of the exemptions so that Ministers may be advised accordingly. After discussions with the NHS, the LA will review periodically the use made of exemptions from the sale or supply regulations with the CPHOs and the RPHOs, along with any other matters arising under the Medicines Act 1968. Officers in the NHS wishing to contribute to this process should refer matters of concern initially to the appropriate CPHO or RPHO.

7.6 **If a Manufacturers Licence is required how can the request for a Qualified Person (QP) be met?**

A person already recognised by MCA as a QP or listed by one of the professional bodies to be eligible to be a QP can be named, or an existing employee can apply to be recognised as a QP. An application can be made either on the basis that the nominee already has the appropriate qualifications and experience or is eligible under the terms of paragraph 1 of Article 24 of EC Directive 75/319. The latter permits a person who, on the date when the Directive was brought into effect, was engaging in the activities of a Qualified Person, to continue to do so. This paragraph of the Directive, in so far as the NHS is concerned, came into effect on the cessation of Crown Immunity, (1 April 1991). Experience in a unit holding a ML (Specials) does not contribute to the experience required to become eligible to be a QP under the EC Directive. This is because no licensed products are manufactured under such a licence.

It is not required to name a QP on a manufacturer's licence for unlicensed medicinal products (ML ("Specials")), but such a licence does require a named Quality Controller and Production Manager.

7.7 **Where do Radiopharmaceuticals stand?**

The production of radiopharmaceuticals within a hospital is an activity which falls within the controls of the Act. Additionally, as an activity which results in the production of medicines or diagnostic agents which are administered to patients, it will be one for which an effective Quality Assurance program is in operation. Both these requirements may be satisfied if the activities are organised in one of the following ways:

either:

a. the activity is licensed by the MCA as "specials" manufacture (and subject to Good Manufacturing Practice requirements)

or:

b. it takes place by virtue of the exemption in section 10 of the Act: that is under the supervision of a pharmacist.

7. GENERAL TOPICS

7.1 During the discussions which took place between the NHS and the MCA on the policy issues arising from the withdrawal of Crown immunity, matters arose which have not been appropriate for incorporation into earlier sections of this guidance. They may be relevant and of interest and are therefore set out below in a question and answer format.

7.2 **How do we know if a medicinal product is a licensed product?**

There must be a PL number on its container. If there is not, that particular product is unlicensed. If in doubt it would be better to pursue the matter back through the chain of supply, and ask the supplier to state whether or not the product is licensed.

7.3 **What about blood and blood products?**

It is open for anyone manufacturing or preparing blood and blood products to apply for product licences and to market his product as a licensed medicinal product. However, blood and blood products prepared in Blood Transfusion Centres will be acceptable as unlicensed medicinal products. These can either be manufactured with a "specials" licence or prepared under a section 9 or section 10 exemption.

7.4 **What are the licensing arrangements if a DHA has several manufacturing units?**

The DHA (or for that matter a RHA or a Self Governing Trust) will hold one licence and name each unit as a manufacturing site on that licence (assuming the units are on separate sites). One licence fee is payable but separate inspection fees are usually charged for each site inspected.

7.5 **Registered Pharmacies are permitted to carry out a limited amount of wholesale dealing, a figure of 5% of turnover has been quoted, what does this mean for the NHS**

A registered retail pharmacy or a pharmacy exempt from registration under section 55 of the Act can wholesale up to 5% of the sterling value of the drugs it purchases without being required to hold a wholesale dealer's licence under section 8(3) of the Act.

Hospital pharmacists may wish to review the operation of activities where these conditions are not currently met.

7.8 Safe custody of Controlled Drugs (CDs)

The requirement to have special cabinets complying with the requirements of Schedule 2 to the Misuse of Drugs (Safe Custody) Regulations 1973 (SI 1973/798) does not apply to NHS hospitals (Regulation 3). It does apply to a retail pharmacy business, ie when the pharmacy is registered with RPSGB.

Regulation 5 imposes a general requirement that Controlled Drugs be kept in a locked receptacle. Thus ward stocks of CDs must be kept in a locked receptacle, but this need not comply with the special requirements in Schedule 2 to these Regulations.

7.9 Home Office licences for wholesale dealing for CDs

Where wholesale supply of CDs is a minor part of the activity of a hospital pharmacy, whether registered with the RPSGB or not, it seems unlikely to cause a problem with the Home Office.

7.10 Registration status of House Officers

A person who holds a qualification which entitles him to be registered, but has yet to complete the relevant period of experience, is entitled to be provisionally registered. While he is completing these requirements he is deemed to be fully registered **so far as is necessary to enable to be engaged in employment in a resident medical capacity in one or more approved hospitals or institutions, but no further**. The effect is that he may issue prescriptions for POMs or CDs only as part of his required duties in that post. He may not order for private patients or for his own use.

7.11 Generic substitution

The prior consent of the prescriber is required. This would normally be achieved through the hospital Drugs and Therapeutic Committee.