MEDICINES ACT LEAFLET

MAL 30

A GUIDE TO THE PROVISIONS AFFECTING DOCTORS AND DENTISTS

MEDICINES CONTROL AGENCY
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MAL 30

MEDICINES ACT 1968
A GUIDE TO THE PROVISIONS AFFECTING DOCTORS AND DENTISTS

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APPENDIX D OUTLINE INFORMATION ON THE LEGAL PROVISIONS AFFECTING THE SUPPLY OF MEDICINAL PRODUCTS TO DOCTORS AND DENTISTS.

These notes are only a general guide and must not be treated as a complete or authoritative statement of the law on any particular case. Copies of the Medicines Act and Regulations made under the Act may be purchased from Government Bookshops.

Prepared by the Department of Health
and Social Security on behalf of the
Health Ministers of the United Kingdom

1. INTRODUCTION

The Medicines Act of 1968 introduced a system of strict controls over the manufacture and distribution of medicinal products.

This leaflet deals with the requirements of the Act as they affect doctors and dentists. It does not discuss the position of manufacturers or suppliers who provide medicines to practitioners, nor does it discuss veterinary practitioners.

Outline information on the legal provisions affecting the supply of medicinal products to doctors and dentists is given in Appenidix D to this leaflet.

2. WHEN IS A LICENCE OR CERTIFICATE REQUIRED?

In general, all dealings in medicinal products - sale, supply, importation, manufacture, assembly, etc - are subject to licensing. Under the Medicines Act there are three types of licence (for products, manufacturers and wholesale dealers) and in addition certificates which relate only to clinical trials.

In most cases these requirements will not affect the individual practitioner as he, or his patient, will acquire medicinal products from a commercial supplier and any licences needed will be the concern of the manufacturer and of the supplier.

In those situations where these requirements do affect practitioners, there are several exemptions which may apply. Some of these exemptions are automatic and others require a notification to be submitted to the Licensing Authority.

3. EXEMPTIONS FOR SUPPLY TO PARTICULAR PATIENTS ON A "NAMED - PATIENT BASIS"

If a practitioner wishes to obtain supplies of an unlicensed product *for administration to a particular patient* the exemption from licensing is *automatic* in the situations listed below.

a. Imported Products

A practitioner does not need a licence to import a sufficient quantity of a product for a course of treatment for a particular patient.

b. Products Manufactured or Assembled by a Practitioner

No product licence or manufacturer's licence is required by a practitioner when he manufactures a product specially for administration to a particular patient of his. He may also

manufacture it for administration to a particular patient of another practitioner if that practitioner asks him to. However, a licence will be required if the practitioner wishes to manufacture a stock for general or emergency use.

The same rules apply to the assembly of medicinal products.

c. Products Manufactured or Assembled to a Practitioner's Order

No licences are required by a practitioner when he arranges the manufacture and/or assembly of a product specially for administration to a particular patient of his. He may also arrange the manufacture and/or assembly of a product for administration to a particular patient of another practitioner if he askes him to. It is also possible under this exemption for a practitioner to have a stock of a product made up for administering to more than one patient. There are, however, limits on the amount: the total stock of unlicensed products held at any one time may not exceed 5 litres of fluid and 2.5 kilograms of solids.

A practitioner who is a member of a group practice providing general medical or dental services may have a stock made up for administering to patients of any member of the group. In this case each of the practitioners in the group may hold stock up to the limits given above.

NB This exemption covering manufacture for stock applies only if the manufacturer holds an appropriate "specials" licence. Individual manufacturers will be able to say whether they can make up orders in this way.

d. Products Not Generally Available

On occasion, a practitioner may wish to obtain a supply of a product that is not of his own devising and that is not generally available eg a new drug that is still undergoing trial. Normally, the supplier of the product would need to hold a product licence before it could be made available. However, the product may be sold or supplied to a practitioner for administration to a particular patient of his provided that:

i. the manufacturer has a "specials licence"

ii. the product is not advertised.

A supply may also be obtained by a practitioner in a group practice who wants the product for administration to a patient of any member of the group.

Whichever of these situations applies it should be remembered that a practitioner prescribing an unlicensed product does so entirely on his own responsibility, carrying the total burden for the patient's welfare and, in the event of an adverse reaction, may be called upon to justify his actions. Under these circumstances it may be advisable for the practitioner to check his position with his medical defence union before prescribing such unlicensed products.

Although in these cases where exemption is automatic no notification needs to be submitted, the Medical Secretariat of the Licensing Authority do welcome being informed of the prescribing of unlicensed products (ie name and address of the patient, the condition to be treated, and the drug to be administered) which they find both helpful and informative. We will also be pleased to see reports of the results of treatment with unlicensed products.

This information should be sent to:

DHSS Medicines Division
Room ~~1117~~ 1418
Market Towers
1 Nine Elms Lane
London
SW8 5NQ

4. SUPPLY TO PRACTITIONERS FOR CLINICAL TRIALS

4.1 AUTOMATIC EXEMPTIONS

A practitioner carries out a clinical trial if he administers a medicinal product to a group of patients primarily to detect what effects it has.

In general, a product may only be imported, sold or supplied, for use in a clinical trial under the authority of a product licence, clinical trial certificate or under the exemption scheme open to suppliers.

A clinical trial is usually arranged by the supplier of the medicinal product who will ask a practitioner to conduct a trial using his product. In these cases it is for the supplier to make an application for a product licence, clinical trial certificate or supplier's exemption, submitting detailed information on the product and, where necessary, the protocol for the trial. If appropriate, the Licensing Authority will then grant the licence, issue the certificate, or approve the exemption, and the practitioner may proceed with the trial. Approval, if given, is usually subject to certain conditions; the holder of the licence, certificate, or exemption is responsible for bringing these conditions to the attention of the practitioner.

In certain circumstances a practitioner may carry out a trial without such an authority and without submitting a notification or application of his own. These are listed below. Such studies are of course the full responsibility of the practitioner concerned, and in the event of an adverse reaction, may be called upon to justify his actions. Under these circumstances it may be advisable for the practitioner to check his position with his medical defence union before starting the trial.

a. **Studies In Healthy Volunteers**

The administration of any substance to healthy volunteers where there is no expectation of benefit (eg to determine the possible existence and nature of any side-effects), does NOT come under the control of the Medicines Act. Thus DHSS authorization is not required before such studies may be carried out.

b. **Clinical Trials Using Licensed Products**

If the only products to be administered in the trial are covered by current product licences for the exact dose form to be used, then no notification for exemption need be submitted to the Licensing Authority.

This is still the case even if the product is to be used in a manner, or for an indication, outside the terms of its licence.

If a specially prepared form of the product is to be supplied by the manufacturer, this must be regarded as an unlicensed product. This includes the situation where one or more licensed products are prepared in a special form to disguise their identity in a "blind" trial.

c. **Clinical Trials Involving Placebos**

An inert placebo is not a medicinal product. If the only other product to be used in the trial is a licensed product (see section (b) above) no notification for exemption need be submitted to the Licensing Authority.

d. **Clinical Trials Using Products Specially Prepared Under the Supervision of a Pharmacist in a Registered Pharmacy, Hospital or Health Centre**

If the trial is to be conducted using only prescribed products specially prepared under the supervision of a pharmacist in a registered pharmacy, a hospital, or a health

centre, then no notification for exemption need be submitted to the Licensing Authority. Responsibility for the quality (and safety in relation to quality) of the product lies with the pharmacist concerned.

4.2 EXEMPTIONS SUBJECT TO NOTICE

This section applies only where section 4.1 does NOT apply.

Clinical Trials Using Unlicensed Products

If a practitioner wishes to conduct a clinical trial using one or more unlicensed products he must notify the Licensing Authority by making use of the Doctors and Dentists Exemption Scheme (the DDX Scheme) giving:

i. his name and address.

ii. the name and address of the supplier.

iii. the name and structure of the product.

iv. details of the proposed trial.

A specimen of the revised standard form for this purpose (Form MLA 162) is illustrated as Appendix B of this leaflet.

If the product is to be supplied from within the United Kingdom, Form MLA 163 (illustrated as Appendix C) should be completed by the supplier and forwarded together with the completed MLA 162.

The practitioner submitting the notification must sign* a declaration that the trial is not to be carried out under the arrangements made by or on behalf of the person who manufactured the product, the person responsible for its composition or the person selling or supplying it, unless such person is the doctor by whom or under whose direction the product is to be administered in the trial.

*If the trial is to be conducted in a hospital, the form must be signed by the Consultant in charge of the patients.

These clinical trial certificate exemptions are allowed on the condition that the practitioner agrees that all serious or unexpected adverse reactions occurring during the course of the trial will be notified to the Licensing Authority immediately.

Important

The Licensing Authority may direct that a particular trial shall not be exempt and may NOT therefore be carried out by the practitioner under the DDX Scheme.

Such a direction, that the trial may not take place, will be issued within 21 days of the date of a completed notification; this period may be extended by the Licensing Authority.

In normal circumstances the Licensing Authority only issues the directive forbidding a trial to take place if the Authority knows of a safety hazard arising from data with which the investigator is unlikely to be familiar or to which he/she cannot have access. Thus, the Doctors and Dentists Exemption Scheme is operated in a way designed to avoid interfering with the decision not to issue the directive (so allowing the proposed trial to proceed) in no way diminishes the professional responsibility of the medical or dental practitioner concerned - nor does it affect the requirements relating to independent ethical approval.

5. APPLICATIONS FOR LICENCES AND CERTIFICATES

Should none of the above exemptions apply in a particular case, an application for a product licence (PL), clinical trial certificate (CTC), or clinical trial certificate exemption (CTX), may be made.

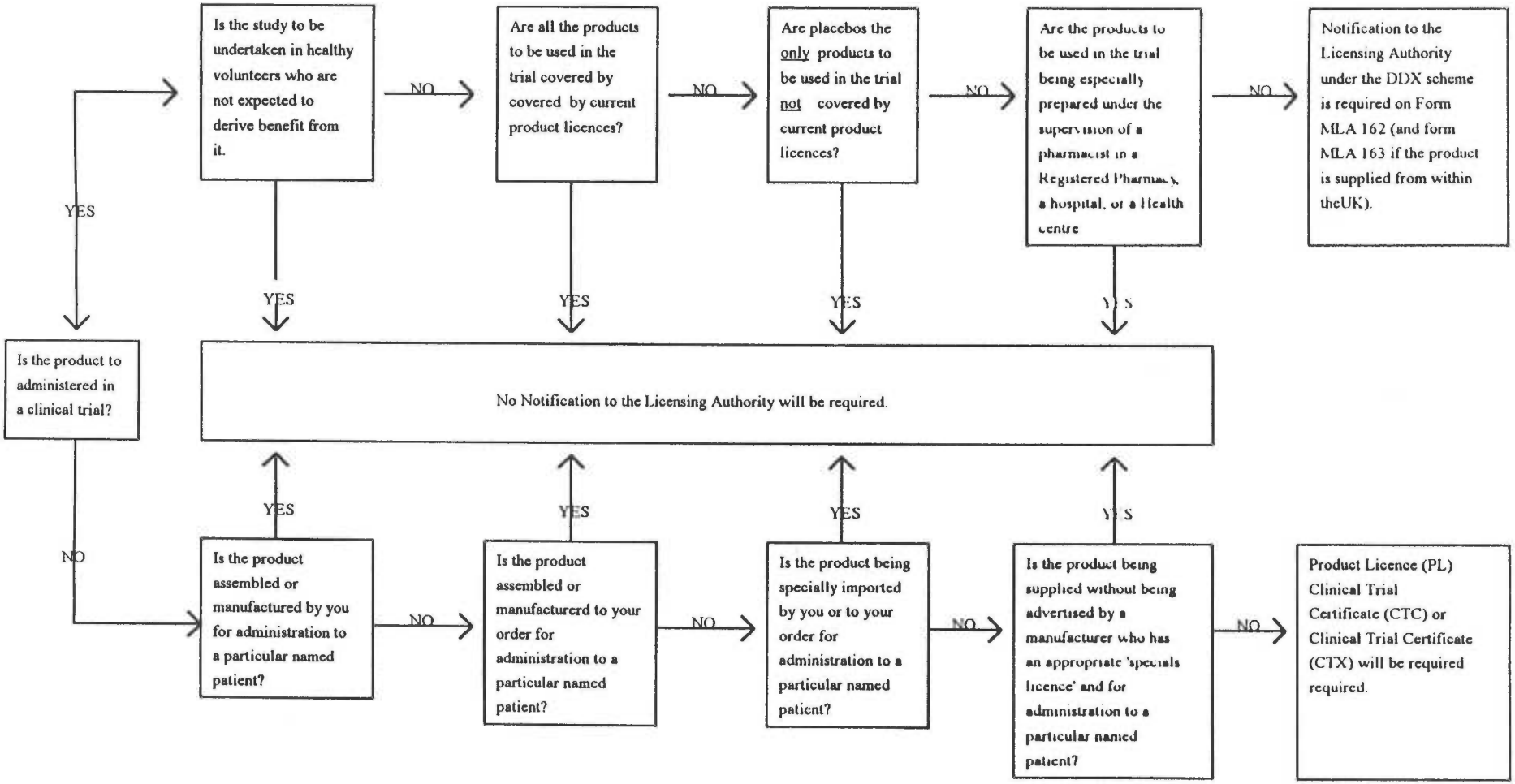
An applicant for a licence or certificate will usually be required to present full information on chemistry and pharmacy, experimental and biological studies and clinical trials. In certain cases, less detailed information may suffice; the professional staff in Medicines Division will be glad to advise on what may be needed for a particular product.

5. FLOW CHART

The flow chart at Appendix A of this leaflet shows the exemptions from the requirements to hold licences and certificates. When the chart indicates that no licence or certificate is required and that an exemption applies, this only refers to the requirement which a doctor or dentist must satisfy. In certain cases the manufacturer or supplier must obtain a PL, a CTC or a CTX.

A GUIDE TO THE LICENSING PROVISIONS AFFECTING DOCTORS AND DENTISTS

FLOW CHART



Please read this Flow Chart in conjunction with the relevantparagraphs earlier in this leaflet

Appendix B

NOTIFICATION BY A PRACTITIONER UNDER THE PROVISIONS OF THE MEDICINES (EXEMPTION FROM LICENCES) (SPECIAL CASES AND MISCELLANEOUS PROVISIONS) ORDER 1972 (SI 1972 No 1200)

Form MLA 162
Page 1

IMPORTANT: This page should be completed in type or in block capitals using black ink.

In accordance with the provisions of the above Order I hereby:

1. Notify the Licensing Authority of my intention to use the undermentioned product in a clinical trial:

   Name of Product: .....

   Name of Supplier: .....

   Address:** .....

   .....

2. Certify that the details given overleaf are a complete and accurate representation of the proposed clinical trial.

3. Certify that this trial is not to be carried out under arrangements made or on behalf of the person who manufactured the product, the person responsible for its composition or the person selling or supplying it unless such person is the doctor or dentist by whom or under whose direction this medicinal product is to be administered in the trial.

   Name: .....

   Address: .....

   .....

   Signature: .....

NB. If this is to be a hospital based trial, this form must be signed by the Consultant in charge of the patients.

** If the above form is to be supplied from within the United Kingdom form MLA 163 should be completed by the supplier and forwarded, along with this form, to:

DHSS Medicines Division
Clinical Trial Exemption Section
Room 1117 1418
Market Towers
1 Nine Elms Lane
London SW8 5NQ

IMPORTANT: This page should be completed in type or in block capitals using black ink.

Form MLA 162
Page 2

Part I

1. Aim of trial:

2. Trial design:

3. Indication/Clinical use to be investigated:

4. Patient Details:

a. Number of patients involved in trial:
b. Age range of patients involved in trial:
c. Will women of child bearing potential be excluded? *YES/NO
d. Will pregnant and lactating women be excluded? *YES/NO

* Please delete

5. Route of administration:

6. Proposed dosage:

7. Duration of drug administration:

8. Duration of trial:

IMPORTANT: This page should be completed in type or in block capitals using black ink

9. Chemical name of drug:

Structure of drug:

10. Pharmaceutical form of product:

11.

a) Does this product hold a current Product Licence *YES/NO
b) Is this product being supplied in its licensed form? *YES/NO
c) If the answers to a) and b) are YES please state the product licence No:

* Please delete PL ...../.....

12. Part II

Name of Practitioner: ..... Tel No: .....

Address: .....

.....

13.

Name of Supplier: ..... Tel No: .....

Address: .....

.....

FOR OFFICIAL USE ONLY

D.I.R

No Dir.	
Dir.	
Auto Ex.	
No. Ex.	

Appendix C

Form MLA 163

DECLARATION BY SUPPLIER IN CONNECTION WITH A NOTIFICATION UNDER THE PROVISIONS OF THE MEDICINES (EXEMPTION FROM LICENCES) (SPECIAL CASES AND MISCELLANEOUS PROVISIONS) ORDER 1972 (SI No 1200)

Name of Product: .....

Product Licence, Clinical Trial Certificate or Clinical Trial Certificate Exemption Number (if applicable) PL/CT/CTX ...../.....

Name of Practitioner: .....

Address: .....

.....

In connection with the supply of the above named product to the above named practitioner for use in a clinical trial, I certify that this product is sold or supplied exclusively for this clinical trial, or if sold or supplied otherwise is sold or supplied in accordance with a product licence, clinical trial certificate, or clinical trial certificate exemption, or in circumstances which enable sale or supply to be carried out otherwise than in accordance with such licence, certificate or certificate exemption.

Name: .....

Signature: ..... Date: .....

on behalf of:

Name of Supplier: .....

Address: .....

.....

Note: When completed this form should be sent to:

MHRA Medicines Division
Clinical Trial Exemption Section
Room ~~117~~ 1418
Market Towers
1 Nine Elms Lane
London
SW8 5NQ

OUTLINE INFORMATION ON THE LEGAL PROVISIONS AFFECTING THE SUPPLY OF MEDICINAL PRODUCTS TO DOCTORS AND DENTISTS

CATEGORY OF EXEMPTION:	LEGAL PROVISION
EXEMPTION FOR SUPPLY TO PARTICULAR PATIENTS ON A "NAMED PATIENT BASIS"	
Imported Products (Para 3.a of MAL)	Medicines Act 1968 Sections 9 & 11
Products Manufactured or Assembled by a Practitioner (Para 3.b of MAL)	" " " "
Products Manufactured or Assembled to a Practitioner's Order (Para 3.c of MAL)	" " " "
Products Not Generally Available (Para 3.d of MAL)	" " " "
SUPPLY TO PRACTITIONERS FOR CLINICAL TRIALS	
AUTOMATIC EXEMPTIONS	
Studies in Healthy Volunteers (Para 4.1.a of MAL)	Not restricted by Medicines Act Medicines Act 1968 Section 11(1) contains the definition of a "clinical trial".
Clinical Trials Using Licensed Products (Para 4.1.b of MAL)	Medicines Act 1968 Section 11
Clinical Trials Involving Placebos (Para 4.1.c of MAL)	Placebos are not medicinal products. Medicines Act 1968 Section 130 contains the definition of a "medicinal product".
Clinical Trials Using Products Specially Prepared Under the Supervision of a Pharmacist in a Registered Pharmacy, a Hospital or a Health Centre (Para 4.1.d of MAL)	Medicines Act 1968 Section 10
EXEMPTIONS SUBJECT TO NOTICE	
Clinical Trials Using Unlicensed Products (Para 4.2 of MAL)	SI 1972 No 1200 - The Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order. SI 1974 No 498 - The Medicines (Exemption from Licences) (Clinical Trials) Order.