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Regulatory Agency

Safeguarding public health

Three overlapping grey hexagons arranged in a triangular pattern. The central hexagon is the largest and contains the title text. The other two are smaller and positioned above and below it, overlapping the central one.

**A guidance note on manufacturer's  
licences authorising a non-orthodox  
practitioner to mix and assemble  
unlicensed medicinal products**

# A GUIDANCE NOTE ON MANUFACTURER'S LICENCES AUTHORISING A NON-ORTHODOX PRACTITIONER TO MIX AND ASSEMBLE UNLICENSED MEDICINAL PRODUCTS

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November 2004

## **Contact or information about this Guidance Note:**

**Licensing Office**  
**Medicines and Healthcare products Regulatory Agency**  
**17-145 Market Towers**  
**1 Nine Elms Lane**  
**Vauxhall**  
**London SW8 5NQ**

**Telephone: 020-7084 2605/2169/2585**  
**Fax: 020-7084 2595**

## **Additional copies of this Guidance Note are available from:**

**The MHRA Information Centre**  
**10th floor**  
**Medicines and Healthcare products Regulatory Agency**  
**Market Towers**  
**1 Nine Elms Lane**  
**Vauxhall**  
**London SW8 5NQ**

**Telephone: 020-7084 2352**  
**Fax: 020-7084 2353**  
**E-mail: [info@mhra.gsi.gov.uk](mailto:info@mhra.gsi.gov.uk)**  
**Web site <http://www.mhra.gov.uk>**

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Medicines and Healthcare products Regulatory Agency  
Market Towers  
1 Nine Elms Lane  
Vauxhall  
London SW8 5NQ

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# INTRODUCTION

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1. The Medicines (Exemptions from Licences) (Special and Transitional Cases) Order 1971 [SI 1971/1450] provides an **exemption from product licensing** for medicines, including homoeopathic medicines, which a **non-orthodox practitioner (NOP)** mixes, assembles and supplies to someone who has asked him, in his presence, to use his judgement as to the treatment that he, or a member of his household requires. Even so, the NOP may need a **manufacturer's licence** authorising mix and assembly of these exempt medicines.

**Note:** *An NOP may be anyone other than a registered doctor, dentist or pharmacist.*

## EXEMPTION FROM PRODUCT LICENSING CONDITIONS

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2. This exemption from product licensing is subject to the following conditions:

- (i) **an NOP must hold a manufacturer's licence**, commonly known as an "NOP Licence", **authorising mix and assembly of medicinal products** for the purpose described in paragraph one above, (unless the mix and assembly of the medicinal product in question is **itself** exempt from licensing - *see* paragraphs four and five below).
- (ii) the products must be mixed and assembled on the premises named on the NOP manufacturer's licence;
- (iii) the medicinal products so mixed and assembled must be products whose retail supply is not restricted to registered pharmacies. That is, they are classed as General Sales List (GSL) medicines, and **not** as Pharmacy (P) or Prescription Only Medicines (POM);
- (iv) any medicinal products *used* in mixing and assembling the products must, unless themselves exempt, be licensed medicinal products or registered homoeopathic products whose retail supply is also not restricted to pharmacies. That is, they are classed as GSL medicines, not as 'P' or 'POM' medicines;
- (v) the product must not be advertised in any way;
- (vi) the product must meet the needs of the person for whom it is made;
- (vii) for a period of *five* years NOPs must keep, and make available for inspection by the MHRA, a record showing the following details for each instance of supply:
  - (a) the source of any product or products used in mixing and assembling the product supplied;
  - (b) the person to whom the product was supplied, and the date;
  - (c) the quantity of each product supplied;
  - (d) details of any suspected adverse reaction to the product, of which they are aware.

## MANUFACTURE (WHICH INCLUDES “MIX AND ASSEMBLY”) OF HERBAL REMEDIES

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3. A **“herbal remedy”** is defined in Section 132 of the Medicines Act 1968 as *“a medicinal product consisting of a substance produced by subjecting a plant or plants to drying, crushing or any other process, or of a mixture whose sole ingredients are two or more substances so produced, or of a mixture whose sole ingredients are one or more substances so produced and water or some other inert substance”*.

4. **An NOP who mixes and assembles a “herbal remedy” in the circumstances described in paragraph one of this Guidance Note does not need a manufacturer’s licence to do so. This is because that person is exempt from the requirement to hold a manufacturer’s licence by virtue of Section 12 of the Medicines Act 1968.**

## MAKING AN APPLICATION

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5. Application for an NOP manufacturer's licence authorising the mix and assembly of medicinal products under the conditions outlined above should be made by completing an Application Form (*see* Appendix 1 of this Guidance Note)

Applications should be sent to:

Medicines and Healthcare products Regulatory Agency  
Licensing Office  
17th Floor  
Market Towers  
1 Nine Elms Lane  
London  
SW8 5NQ

6. The MHRA aims to process new applications within 90 days and variations to licences within 30 days.

# REPORTING CHANGES TO THE LICENSING AUTHORITY

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7. Holders of NOP manufacturer's licences should report, without delay, the following matters to the MHRA:

- (a) any change of address;
- (b) details of any *serious* adverse reaction to products supplied by the holder.

Reports should be sent to:

Medicines and Healthcare products Regulatory Agency  
Head of Section  
Licensing Office  
17-145 Market Towers  
1 Nine Elms Lane  
London  
SW8 5NQ

## **FEES**

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8. A licence application fee is payable. Remittances should not accompany applications, as instructions for payment will be sent separately.

## **COMPLYING WITH EC GUIDANCE ON TSE**

9. Practitioners who prepare remedies (excluding herbal remedies) for individual patients during the course of a business must demonstrate that the unlicensed medicines produced comply with the European Commissions 'Notes for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via medicinal products' and future updates, in accordance with, The Unlicensed Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2003 [SI 2003/1680]. See the MHRA's interim guidance, 'Minimising the risk of Transmission of Transmissible Spongiform Encephalopathies via Unlicensed Medicinal Products for Human Use', available from the MHRA website, [www.mhra.gov.uk](http://www.mhra.gov.uk)

## APPENDIX 1- SAMPLE APPLICATION

### APPLICATION OF A NON-ORTHODOX PRACTITIONER FOR AUTHORISATION TO MIX AND ASSEMBLE MEDICINAL PRODUCTS

*[Please use capital letters]*

1. **Name and address**
2. **Address(es)** of the storage site or sites where I intend to hold products to be used in mixing and assembling medicinal products.
3. **Address(es)** of premises where I intend to mix and assemble medicinal products of a class which may be lawfully supplied from premises other than a registered pharmacy.
4. **Address(es)** of premises where I intend to supply medicinal products I have mixed and assembled to people who have asked me, in my presence, to use my judgement as to the treatment they or a member of their household require.

*[Declaration]*

**“I apply for an authorisation permitting me to mix and assemble medicinal products of a class that may be lawfully supplied from premises other than a registered pharmacy. These medicinal products will only be supplied to persons who have asked me, in my presence, to use my judgement as to the treatment they, or a member of their household require. I will inform the licensing authority of any material change to the terms of authorisation should I cease to practice.”**

*[Signed]*

*[Date]*

## APPENDIX 2 SAMPLE LICENCE

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**MEDICINES ACTS 1968 AND 1971  
LICENSING THE MIX AND ASSEMBLY OF  
MEDICINAL PRODUCTS FOR THE PURPOSES OF  
ARTICLE 2-(2)( e) of SI 1971/1450**

[ *Name and Address* ]

[ *Licence Number* ]

**The licence described above has been granted under, and subject to, the provisions of the Medicines Act 1968 and 1971 to the person named above.**

It authorises the holder to mix and assemble and supply, at the premises on the licence application, medicinal products which:

- are unlicensed;
- are medicinal products of a class which may be lawfully supplied by way of retail from premises other than a registered pharmacy; and
- are for supply to persons who have asked the holder, in his presence, to use his judgement as to the treatment they, or a member of their household, require.

**Certifying Officer**

A person authorised to  
sign on behalf of the  
**Secretary of State for Health**

## APPENDIX 3

# THE CLASSIFICATION OF PRODUCTS

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**Introduction** The Medicines Act divides medicines for human use into three categories for the purpose of retail sale or supply: General Sale List (**GSL**), Pharmacy (**P**) and Prescription Only Medicine (**POM**).

**General Sale List** The purpose of this list is to specify those medicinal products which can be sold with reasonable safety without the supervision of a pharmacist, for example in a supermarket.

**Pharmacy** Pharmacy medicines do not require a prescription and may be sold or supplied only in a registered pharmacy hospital or health centre by or under the supervision of a pharmacist. The package gives information on dosage.

**Prescription Only Medicine** These medicines may be sold or supplied only from a registered pharmacy [or hospital or health centre under the supervision of a pharmacist] and in accordance with a prescription issued by a doctor or dentist. The substances so restricted are those whose use needs to be supervised by a medical or dental practitioner because the condition being treated requires diagnosis by a doctor or dentist and because they may produce toxic reaction or physical or psychological dependence, or may be a hazard to the health of the community. The criteria for these restrictions are set out in the Medicines Act.

**The general rule** The general rule is that all licensed medicines are P unless otherwise designated. Substances are listed in the GSL and POM orders on the advice of committees set up by the Medicines Commission. These lists are available to the public and they are revised periodically when new medicines come on the market.

**Source** *Towards Safe Medicines: a guide to the control of safety, quality and efficacy of human medicines in the United Kingdom.* London: MCA, 1997