

**EXPLANATORY MEMORANDUM TO  
THE MEDICINES (EXEMPTIONS AND MISCELLANEOUS AMENDMENTS)  
ORDER 2009**

**2009 No. 3062**

1. This explanatory memorandum has been prepared by the Medicines and Healthcare products Regulatory Agency (MHRA) part of the Department of Health and is laid before Parliament by Command of Her Majesty.

**2. Purpose of the instrument**

2.1 This Order creates new exemptions from the restrictions imposed by sections 7 and 8 of the Medicines Act 1968 in relation to licensing and manufacture of medicinal products. It also amends the Prescription Only Medicines (Human Use) Order 1997 to allow members of Her Majesty's armed forces to supply or administer prescription only medicines (POMs) in some circumstances in so far as this is necessary. The Order further amends the Medicines (Pharmacy and General Sale - Exemption) Order 1980 to allow members of Her Majesty's armed forces to supply pharmacy (P) and general sale list medicines in so far as this is necessary. Finally, the Order makes provision for registered dispensing opticians to sell or supply eye drops or ointment containing Chloramphenicol.

**3. Matters of special interest to the Joint Committee on Statutory Instruments**

3.1 None.

**4. Legislative Context**

4.1 Under Sections 7 and 8 of the Medicines Act 1968, medicinal products cannot be manufactured, sold, supplied or procured except in accordance with an appropriate licence. There are limited exemptions from these restrictions to allow for the manufacture, supply and administration of unlicensed medicines.

4.2 The Order amends two Orders relating to the sale, supply and administration of medicines -

- The Prescription Only Medicines (Human Use) Order 1997 (the POM Order) which specifies the description and classes of medicines that subject to exemptions in the Order may only be sold or supplied in accordance with the prescription of an appropriate practitioner (see section 58(2) of the Medicines Act);
- The Medicines (Pharmacy and General Sale – Exemption) Order 1980 which provides exemptions from the restrictions on sale and supply of medicines under sections 52 and 53 of the Medicines Act 1968. In particular, it provides exemptions from the requirements that POMs

and medicines classed as pharmacy (“P”) medicines may only be sold or supplied on registered pharmacy premises by or under the supervision of a pharmacist. The Order also provides exemptions from the requirement that medicines classed as general sale list (GSL medicines) may only be sold from non-pharmacy premises provided they are lockable and the products are pre-packed.

### **Exemptions from sections 7 and 8 of the Medicines Act**

- 4.3 Mixing medicines together, where one is not a vehicle for the administration of the other, falls into the Medicines Act definition of “manufacture” and creates a new unlicensed medicine. As a new product is being manufactured, a manufacturers’ licence is required by the person undertaking the mixing.
- 4.4 Under existing exemptions in the Medicines Act, doctors and dentists can prepare an unlicensed medicine or order its preparation. Pharmacists may also prepare or dispense unlicensed medicines in accordance with a doctor’s or dentist’s prescription. The amending Order will allow doctors to instruct nurses and pharmacists to mix medicines. It will also exempt nurse and pharmacist independent prescribers and supplementary prescribers acting in accordance with a clinical management plan for an individual patient, from the restrictions in sections 7 and 8 of the Act to allow them to mix medicines for administration or direct others to do so.

### **Members of Her Majesty’s armed forces**

- 4.5 The amending Order will allow members of Her Majesty’s armed forces to supply and administer medicines provided:
- this is in the course of carrying out any function as a member of Her Majesty’s armed forces; and
  - the person supplying or administering the drug is satisfied that this could not be done by some other person who is legally qualified to do so; and
  - the supply or administration is in an emergency or to prevent ill-health - but only in so far as this is necessary.

### **Registered Dispensing Opticians**

- 4.6 The amending Order will exempt registered dispensing opticians from the requirement that pharmacy medicines can only be sold or supplied on registered pharmacy premises by or under the supervision of a pharmacist. The exemption will only apply in relation to the sale or supply of eye drops or ointment containing Chloramphenicol below a certain strength

and where this is done in the course of the Optician's professional practice.

### **Related legislation**

- 4.7 The amending instrument is being laid with a related SI (the Medicines for Human Use (Miscellaneous Amendments) (No.2) Regulations 2009).

## **5. Territorial Extent and Application**

- 5.1 This instrument applies to all of the United Kingdom.

## **6. European Convention on Human Rights**

- 6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

## **7. Policy Background**

- 7.1 The amendments relating to the mixing of medicines recognise that the current legal position has the potential to obstruct the provision of effective and timely patient care. This is particularly the case in palliative care. The amendments ensure that healthcare professionals engaging in the long-standing accepted practice of mixing medicines prior to administration are acting within the law.
- 7.3 The amendments relating to the supply and administration of medicines by Her Majesty's armed forces are intended to address situations where registered healthcare personnel are not available to provide either immediate medical care or to treat or prevent ill health at all times during military operations, exercises or other activities within or outside the UK. The amendments relax the requirements so that in those specified and limited circumstances any member of Her Majesty's armed forces may supply or administer medicinal products.
- 7.4 The amending Order will allow registered dispensing opticians to sell or supply products containing Chloramphenicol which are not subject to prescription control and are used for the treatment of bacterial conjunctivitis - a common condition.
- 7.5 The proposals were subject to consultation and advice to Ministers by the Commission on Human Medicines. For the mixing proposals, the majority of responses (162 out of 169) supported the proposals in principle. There were 12 replies to the proposals for the armed forces of which 9 expressed broad support. The MHRA received 86 replies in response to the proposals for dispensing opticians, 78 of which were supportive.

## **8. Consultation Outcome**

- 8.1 A three month consultation on the proposals for mixing medicines ran for three months from 5 December. There were 187 replies to the consultation and 162 of these supported the proposals.
- 8.2 Three month consultations were also undertaken for the proposals in relation to dispensing opticians and supply of medicines by members of her Majesty's armed forces. All consultations were circulated to a range of interested organisations and the outcomes considered by the Commission on Human Medicine.
- 8.3 For dispensing opticians, the vast majority of responses to the consultation were supportive. It was originally proposed to restrict the sale or supply of Chloramphenicol to those dispensing opticians who were additionally qualified as contact lens specialists. However, following the consultation, the profession's regulatory body (the General Optical Council), requested that the proposal be extended to all registered dispensing opticians.
- 8.4 For the consultation relating to the armed forces, the MHRA received 12 replies. Nine of these were broadly supportive and the remainder either made no comment or expressed no preference.

## **9. Guidance**

- 9.1 The Department of Health and the National Prescribing Centre are developing guidance on the mixing of medicines in clinical practice. The General Optical Council and dispensing opticians' representative bodies will put guidance in place about the use of Chloramphenicol. The situations in which members of Her Majesty's forces can supply or administer medicines will be clearly laid down by the Surgeon General's Department.

## **10. Impact**

- 10.1 Impact assessments have not been prepared for these proposals as they do not impose a cost compliance on business, charities or the voluntary sector.
- 10.2 The impact on the public sector is principally to benefit patient care.

## **11. Regulating small business**

- 11.1 The amending Order will enable the many dispensing opticians who operate as sole practitioners to sell or supply Chloramphenicol directly to patients.

## **12. Monitoring and review**

- 12.1 The changes in this instrument are aimed at benefiting patient care. In line with the Better Regulation Agenda, the instrument will be reviewed in three years time to assess whether it is still fit for purpose.

## **13. Contact**

- 13.1 Anne Ryan at the MHRA tel: 0207 084 2392 can answer any queries regarding this instrument.