

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY (MHRA)

STATEMENT ON NON-MEDICAL PRESCRIBING AND MIXING MEDICINES IN PALLIATIVE CARE

Background

The MHRA is responsible for the enforcement of the Medicines Act 1968 and related secondary legislation. Initially, the Agency was asked to advise on the legalities of physiotherapists mixing two licensed medicines in a syringe prior to administration under a Patient Group Direction (PGD). The PGD issue was straightforward as the legal framework for PGDs excludes unlicensed drugs. The Agency subsequently contributed to a position paper published by the Chartered Society of Physiotherapists (CSP) which set out the legal position and alternatives to mixing medicines under a PGD.

.Section 132 of the Medicines Act 1968 defines manufacture. The section provides:

“ " 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.”

This definition would, for example, allow a tablet to be crushed or a capsule opened and mixed with a solution to make it easier for the patient to take. It would also enable mixing substances with, for example, water for injection prior to parenteral administration. However mixing two licensed medicines, where one is not a vehicle for the administration of the other, falls within the definition of manufacture and results in a new, unlicensed product being administered. In addition, as a new product is being manufactured, a manufacturer's licence would be required.

At present there are exemptions in medicines legislation to allow for the manufacture, supply or administration of unlicensed medicinal products (whether or not a particular exemption applies also depends upon whether the product is within the scope of Directive 2001/83/EC). In brief, the exemptions apply to the following :

- products supplied in response to a bona fide unsolicited order, formulated in accordance with the specification of a doctor, dentist or supplementary prescriber and for use by his individual patients on his direct personal responsibility in order to fulfil the special needs of those patients. These products are known as “specials”.
- products prepared by a pharmacist in accordance with a medical prescription (“magistral formula”) or in accordance with the specification or monograph of a pharmacopoeia (“officinal formula”). These products are sometimes referred to as “extemporaneously prepared” medicines.
- products “specially prepared” for individual patients of a doctor or dentist under section 9 of the Medicines Act 1968.

Non-medical prescribing in palliative care

Following publication of the CSP statement, the Agency received a number of enquiries from palliative care practitioners seeking clarification of the law in relation to non-medical prescribers prescribing two or more medicines for administration via a syringe driver. The Agency’s position is that the advice it had given about mixing of medicines in physiotherapy practice applied equally to the same practice in palliative care. Under medicines legislation independent nurse and pharmacist prescribers are allowed to prescribe any licensed medicine for any medical condition (currently there are certain restrictions on controlled drugs pending forthcoming amendments to the Misuse of Drugs Regulations (MDR)) but Nurse and Pharmacist Independent Prescribers are not authorised to prescribe unlicensed medicines.

The Agency are aware from discussions with palliative care interests that it is long standing accepted practice in this field to prescribe a mixture of licensed medication for administration, usually via a syringe driver. The mixing and administration may be undertaken by the prescriber or by another, usually a nurse, working in accordance with the directions of the prescriber. We understand there is a body of evidence supported by many years of clinical experience that mixing certain medicines in a syringe driver is safe and effective.

The MHRA recognise that palliative care requires special consideration and we would not wish to obstruct the provision of effective pain relief to patients. In September therefore, the MHRA will be seeking provisional advice from the Commission on Human Medicines (CHM) on possible options for changes to medicines legislation in advance of the usual public consultation procedures

required under the Medicines Act 1968. The CHM will be asked to provide formal recommendations to Ministers following the completion of that public consultation.

In the meantime the MHRA would not consider taking enforcement action for breaches of medicines legislation by a Nurse or Pharmacist Independent Prescriber engaging in the long standing accepted practice of prescribing and administering (and providing directions to others to administer) a mixture of licensed medication via a single injection or a syringe driver unless it would be in the public interest to do so. This also applies to those mixing and administering medicines in accordance with the directions of the prescriber. Each case would be considered individually.