

Gateway ref: 14330

## **Mixing of medicines prior to administration in clinical practice: medical and non-medical prescribing**

The Medicines and Healthcare products Regulatory Agency (MHRA) published consultation (MLX 356) on mixing of medicines in palliative care in December 2008. To consider the issue of mixing of medicines in clinical practice, including the results of the consultation, the Commission on Human Medicines (CHM) established a Working Group. Existing legislation already enables pharmacists to mix medicines to the specification of a doctor or dentist, or mixing can be undertaken by a person holding a manufacturer's licence. To meet the needs of clinical practice within a regulatory framework, the CHM Working Group made recommendations, which were fully endorsed by the CHM and Ministers. These recommendations form the basis of changes to medicines legislation which now enable:

- Doctors and dentists, who can already mix medicines themselves, to direct others to mix
- Nurse and Pharmacist Independent Prescribers to mix medicines themselves and to direct others to mix
- Supplementary Prescribers to mix medicines themselves and to direct others to mix, but only where that preparation forms part of the Clinical Management Plan for an individual patient
- Nurse and Pharmacist Independent Prescribers to prescribe unlicensed medicines for their patients, on the same basis as doctors and dentists (and supplementary prescribers if part of a Clinical Management Plan for an individual patient).

The legal changes also define “mixing” as “the combination of two or more medicinal products together for the purposes of administering them to meet the needs of a particular patient.

**These changes apply not only to palliative care, but to all clinical areas where the mixing of medicines prior to administration is accepted practice and supported by the employer’s policies for the delivery of healthcare.**

No changes are intended to the existing legal requirements for Patient Group Directions and medicines resulting from the mixing of medicines

(other than 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) cannot be supplied or administered under PGD arrangements.

The Working Group agreed a number of parameters, principles and key points which the CHM also endorsed: they are intended to guide those prescribers who need to prescribe, administer or direct others to prepare and administer medicines intended to be mixed before administration. These points are outlined below, and apply to all clinical practice, not just palliative care.

### **Controlled Drugs**

The MHRA has already issued a statement advising that it would not consider taking enforcement action against those prescribing and administering mixtures of licensed medicines in clinical practice, unless it would be in the public interest to do. This includes controlled drugs and the Home Office is aware of the position.

The MHRA has also approached the Home Office and the Advisory Council for the Misuse of Drugs (ACMD) with the Commission's recommendations that corresponding amendments for controlled drugs are made to the Misuse of Drugs Regulations. Meantime, existing good practice arrangements should continue on mixing before administration which includes a controlled drug.

## **Guidance Points on Prescribing and Administration of Medicines Intended to be Mixed prior to administration**

Following detailed discussion by the Commission on Human Medicines (CHM), the following points should be carefully considered when prescribing and administering medicines which are intended to be mixed prior to administration.

In some settings, including End-of-Life Care and intensive care, it will be in the patient's best interests for medicines to be mixed, for instance through a syringe drive or single line.

### **Parameters**

The Mixing of medicines should:

- only be undertaken in the best interests of the patient
- be avoided where possible
- only be done by a person competent and willing to do so
- take place in a pharmacy, where possible.

### **Principles**

The CHM has agreed that the following principles on mixing of medicines should apply:

- Mixing should be avoided where possible. It must only be undertaken when clinically appropriate and essential to meet the needs of the patient. It should not be undertaken for the convenience of a health professional.
- The instruction/ direction to mix must be in writing.
- The prescriber takes responsibility for satisfying himself or herself that clinical governance arrangements are in place to ensure that the "mixer" is competent to undertake the task safely and effectively - especially within a non-hospital environment.
- The person mixing the medicines must be competent.
- No-one should be obliged to mix and administer medicines if they do not feel competent or content to do so.

## **Key Points - Prescribing and administration of medicines intended to be mixed**

- Medicines should not be prescribed for mixing (whether for parenteral or oral administration) unless essential to meet the needs of the patient
- Licensed products should be used for preference
- If mixing is necessary, the product should, as a preference and where possible, be prepared in a pharmacy by or under the supervision of a pharmacist or ordered from a person holding a manufacturer's licence.
- Prescribers should seek advice from a pharmacist in deciding whether there are alternatives to administering mixed medicines for individual patients or, if not possible, from an authoritative source of guidance on the combination of medicines.
- Prescribers should seek advice from a pharmacist in determining which substance(s) can be mixed and in what dosages or, if not possible, from an authoritative source of guidance on the combination of medicines
- If mixing must be undertaken in a "near-patient" situation, prescribers should clearly identify which substance(s) should be mixed and in what dosages.
- It is recognised that there are particular circumstances, for example for a patient at the end of life and intensive care, where mixing will be in the patient's best interests as it will provide the simplest and most efficient way of managing the patient's symptoms.
- Injections and sterile medicines prepared in near-patient areas should normally be administered immediately
- A medicine mixed in a near-patient area should be prepared only for individual patients and be clearly labelled with the direction that it is to be used immediately and, if not, labelled with an expiry period.
- Medicines should only be prescribed for administration by injection when no other route is suitable [NB: refer to NICE guidance on risk assessments for IV/"general" injections].
- The Commission on Human Medicines recommends prescribers should satisfy themselves that clinical governance arrangements are in place, to

ensure that those undertaking the mixing of medicines they have prescribed are professionally competent and will take full professional and clinical responsibility for their decisions and actions.

- Prescribers need to take account of their local employer's policy and guidance on mixing of medicines and the prescribing of unlicensed medicines, eg NHS Trust or PCT.

### **Unlicensed Medicines**

For clarification, separate legislative requirements govern the ordering of unlicensed medicines – that is, a medicine which does not have a valid Marketing Authorisation (licence) in the UK. These are often referred to as “specials”. Such products are unlicensed relevant medicinal products supplied in response to bona fide unsolicited orders. They are formulated in accordance with the specifications of a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber (or supplementary prescriber if the unlicensed medicines are part of the Clinical Management Plan for an individual patient) for use by his individual patients on his direct personal responsibility, and in order to fulfil "special needs". Such products must be supplied in accordance with the requirements of the legislation; in particular, if the product is made in the UK, it must be manufactured by a person holding a manufacturer's licence for this purpose (a manufacturer's specials licence). “Specials” may be imported into the UK only by a licensed wholesale dealer.

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