

## **MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY (MHRA)**

### **REVISED STATEMENT ON MEDICAL AND NON-MEDICAL PRESCRIBING AND MIXING MEDICINES IN CLINICAL PRACTICE**

1. The Agency has now published the outcome of MLX 356 on the mixing of medicines in palliative care together with the Commission on Human Medicines' recommendations for changes to medicines legislation. The Commission's recommendations have been accepted by Ministers. The proposed changes will apply not only to palliative care but to all clinical areas where the mixing of medicines is accepted practice. We intend to amend the law before the end of the year as follows:

- **To allow Doctors and dentists (who can already mix medicines themselves) to direct others to mix (other than a pharmacist under existing legislative provisions, or by a person holding a manufacturer's licence)**
- **To allow Non-medical prescribers to mix medicines themselves and direct others to mix (other than a pharmacist under existing legislative provisions, or by a person holding a manufacturer's licence)**
- **To allow Nurse and Pharmacist Independent Prescribers to prescribe unlicensed medicines for their patients on the same basis as doctors and supplementary prescribers.**

The MHRA are also approaching the Home Office and the Advisory Council for the Misuse of Drugs (ACMD) with the Commission's recommendations that corresponding amendments are made to the Misuse of Drugs Regulations.

2. The Agency has already issued a statement advising that we would not consider taking enforcement action against those prescribing and administering mixtures of licensed medicines in palliative care unless it would be in the public interest to do. As we now intend to regularise the position of those engaged in the prescribing and mixing of medicines in other areas of clinical practice, we are extending our advice to cover these situations. Again, the position on enforcement action is subject to the public interest test and each case would be considered individually.