OUTCOME OF THE CONSULTATION EXERCISE ON PROPOSALS FOR REGULARISING THE POSITION OF THOSE MIXING AND ADMINISTERING MEDICINES IN PALLIATIVE CARE

Background

1. In September 2008, the Commission on Human Medicine (CHM) was asked to advise the MHRA on the implications for current clinical practice, especially in palliative care, of the definition of "manufacture" contained in the Medicines Act 1968. Briefly, under current legislation and except in very restricted circumstances, mixing drugs together, where one is not a vehicle for the administration of the other, creates an unlicensed medicine. Furthermore, the legislation requires the person undertaking this preparation, unless an exemption applies, to hold a manufacturer's licence.

2. In palliative care, it was usual to mix two or more medicines in a syringe driver prior to administration and this preparation could take place in a patient's own home. The Agency had recognised that the legal position had the potential to obstruct the provision of effective pain relief and symptom control to patients receiving palliative care. As a holding measure the Agency had issued a statement to the effect that they would not consider taking enforcement action for breaches of medicines legislation by doctors, Nurse or Pharmacist Independent Prescribers who were engaged 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.

3. As a more permanent measure, the Agency sought the CHM's views on a public consultation proposing changes to legislation. The CHM considered four possible options, focussing on palliative care. These were:

- Option A - "Do nothing"
- Option B - amend the definition of "manufacture" in the Medicines Act
- Option C - develop a statutory formulary for "mixing" in palliative care
- Option D - enable Nurse and Pharmacist Independent Prescribers to order "specially prepared" products for their individual patients and to enable non-prescriber nurses/pharmacists to mix those medicines prior to administration.

4. CHM's provisional view was that Option D seemed favourable. The proposal would be based on the understanding that all concerned are professionally competent and would take full professional and clinical responsibility for their actions.

5. Consultation letter MLX 356 was issued on 5 December 2008 with a deadline for comments of 27 February 2009. It was circulated to a range of interested organisations throughout the UK and copies appeared on the MHRA website. The MHRA received 189 responses of which 27 related to the devolved administrations. Officials in the devolved administrations have agreed that this paper should cover all the replies rather than providing a

breakdown of those relating to individual countries. The replies can be broadly categorised as follows:

Medical and Pharmaceutical Organisations	16
Palliative Care organisations	7
Other Professional bodies/interests	9
Other Palliative Care interests	60
Other Organisations (including NHS bodies)	75
Individuals	22

One hundred and sixty two (162) of the replies supported the proposals in principle. A substantial majority of these expressed a preference for adopting Option D. Twenty six (26) responses made no comment on the proposals or expressed no specific preference. There was also support for extending the proposals to allow mixing in other areas of clinical practice. Some concerns were raised in the responses about particular aspects of the proposals and these are identified below. The remaining response, from the British Medical Association (BMA), was clearly supportive of Option D but they did not support the proposal to allow nurses to possess and compound controlled drugs.

6. In tandem with the public consultation, the CHM established a Working Group (WG) to discuss the proposals in detail as well as other areas of practice where mixing of medicines occurs. The WG also considered the results of the public consultation in depth and invited a number of external experts to either attend meetings or offer views and advice in writing. It became clear from external advice and discussion at the WG meetings that "mixing" was not restricted to palliative care and that option D as presented initially would not meet current clinical need.

7. The WG reported to the CHM in May 2009. The WG recommended that:

> **Doctors and dentists (who can already mix medicines themselves) should be able to direct others to mix (other than a pharmacist under existing legislative provisions, or by a person holding a manufacturer's licence)**
>
> **Non-medical prescribers should be able to mix medicines themselves and should be able to direct others to mix (other than a pharmacist under existing legislative provisions, or by a person holding a manufacturer's licence)**
>
> **it was a logical step 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, provided CHM agree with the proposals of the WG, should approach the Home Office and the Advisory Council for the Misuse of Drugs (ACMD) with CHM's recommendations that**

corresponding amendments are made to the Misuse of Drugs Regulations.

8. The recommendations would be supported by the development of guidance to aid those involved in the “mixing” of medicines whether as prescribers or administrators. The Group also proposed that research should be commissioned to develop authoritative national advice on “mixing” of medicines to encompass compatibility and stability data and appropriate dilutions.

9. The CHM fully endorsed the recommendations and the principles that had guided the Working Group’s deliberations. Those principles made clear that the mixing of drugs should be avoided unless essential to meet the needs of the patient, and that those involved in both the prescribing and actual mixing should be competent to do so and take full professional and clinical responsibility for their actions. In addition such actions must be within the governance structures and guidance of the employing authority and of the relevant statutory bodies.