

Advisory Council on the Misuse of Drugs

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James Brokenshire MP 2 Marsham Street London SW1P 4DF

27th July 2010

Dear Minister,

Re: Mixing of Medicines in Clinical Practice

The Advisory Council on the Misuse of Drugs (ACMD) has had the opportunity to consider the issue of 'mixing of medicines in clinical practice' which has implications for the Misuse of Drugs Regulations 2001 (as amended) (2001 Regulations) as it relates to controlled drugs. I apologise that this letter has not reached you sooner.

The issue was first brought to our attention in October 2008 by the Medicines and Healthcare Products Regulatory Agency (MHRA). It relates to the lawful provision of medicine by healthcare professionals where drugs are mixed together prior to administration. In palliative care it is usual to mix two or more medicines in a syringe driver prior to administration. The MHRA realised that the legal position under the medicines and misuse of drugs legislation needed to be regularised to ensure the provision of effective pain relief and symptom control to patients receiving palliative care. The MHRA subsequently consulted the Commission on Human Medicine's (CHM) and the public, with Home Office's contribution in relation to controlled drugs.

Having considered this matter at key stages in the MHRA's process to find an effective solution, at its 14th December 2009 the ACMD agreed with the option that the MHRA proposed, supported by the CHM: '[to] Enable Nurse and Pharmacist Independent Prescribers to specially prepare products for their individual patients and direct nurses and pharmacists and others who are not prescribers to mix drugs prior to administration. At the same time, enable doctors to direct nurses, pharmacists and others to mix on a similar basis.' This will require an amendment to the 2001 Regulations to allow practitioners to give directions to others to compound controlled drugs in clinical practice;

allow nurse independent prescribers and supplementary prescribers to compound controlled drugs and, together with and pharmacist independent prescribers direct others to do so.

It is the judgement of the ACMD that the option proposed by the MHRA (as set out above) is an appropriate response to this issue. It is our assessment that it does not increase the risk of diversion of controlled drugs in the community though of course, the continued rigorous monitoring of the use of controlled drugs and that the principles set out in the 'Report of the CHM Working Group on Mixing of Medicines' must be adhered to.

Yours Sincerely,

Professor Les Iversen

cc: David Oliver (Head of Drug Strategy)
Medicines and Healthcare products Regulatory Agency (MHRA)