



# U.K. Psychiatric Pharmacy Group

*From:* Graham Newton  
Pharmacy Department  
Mossley Hill Hospital  
Park Avenue  
Liverpool L18 8BU

*Telephone:* 0151-250 6011

*Facsimile:* 0151-719 0670

*e-mail:* graham.newton@merseycare.nhs.uk

*website:* www.ukppg.org.uk

Mr Roy Drepaul  
MHRA  
16-139  
Market Towers  
1 None Elms Lane  
LONDON  
SW8 5NQ

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Dear Mr Drepaul

**MLS 298: Supplementary prescribing: use of unlicensed medicines, reformulation of licensed products and preparations made from active pharmaceutical ingredients and excipients**

Please consider the following comments as the submission by the committee of the **United Kingdom Psychiatric Pharmacy Group** on behalf of it's membership.

*1. the POM order is amended to allow supplementary prescribers to prescribe or administer an unlicensed PM (paragraph 11)*

We welcome this proposal. There are a number of drugs that specialist mental health pharmacist supplementary prescribers could prescribe within the framework of a clinical management plan including pirenzepine for the management of hypersalivation induced by clozapine and fluspiriline, an aqueous antipsychotic depot medication. Our submission to the consultation on MLX 268 similarly supported this proposal; in the light of this we felt that the final scope of supplementary prescribing was restricted without the option to prescribe unlicensed medications.

We would add that where an unlicensed medication is to be prescribed it should be explicitly named in the clinical management plan or should be explicitly listed in the algorithm or guideline that the clinical management plan refers to. We consider it is not appropriate for unlicensed medications to be referred to in a vague manner; for example, pirenzepine should not be prescribable if the clinical management plan, guideline or algorithm refers to 'antimuscarinics'. Similarly fluspiriline should not be referred to generically as a depot antipsychotic.

We believe that there are only some specific situations in mental health where such unlicensed drugs are clinically appropriate. Since the safety of the patient should be paramount the criteria that justify the use of an unlicensed drug should be explicit and clearly defined.

*2. NHS regulations be amended to allow supplementary prescribers in the NHS in England to prescribe unlicensed medicines*

We welcome the proposal.

*3. Schedule 1 to the 1994 regulations be amended to permit the supply of an unlicensed relevant medicinal product in response to a bona fide unsolicited order, if the product is formulated in accordance with the specification of a supplementary prescriber and is for the use by his or her patients (paragraph 12 – 15)*

We welcome the proposal.

*4. an order be made under section 15 of the Medicines Act 1968 to enable the preparation or dispensing of a product by, or under the supervision of, a pharmacist in a registered pharmacy, in a hospital or health centre in accordance with the prescription of a supplementary prescriber (paragraph 16-19)*

We welcome the proposal.

We are concerned at the potential for confusion to arise as the dispensing pharmacist will be unable to distinguish between a prescription written by a nurse in their capacity as an extended formulary nurse - or a supplementary – prescriber. However, we believe that this risk will already have been considered as it is not new to this consultation exercise.

*5. there is no need for the wholesale supply of an unlicensed medicines direct to a supplementary prescriber (paragraph 20)*

We have no comment on this proposal

Yours sincerely

Graham Newton, BSc(Hons), DipClinPharm, MRPharmS, MCMHP  
*Chairman, United Kingdom Psychiatric Pharmacists Group*