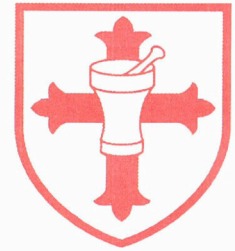




GHP

*Guild of
Healthcare
Pharmacists*



21st September 2010

Roy Drepaul,
16/139
Medicines and Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London, SW8 5NQ.

Dear Mr Drepaul

MLX 370: INTENTION TO FURTHER AMEND THE MEDICINES FOR HUMAN USE (PRESCRIBING BY EEA PRACTITIONERS) REGULATIONS 2008 TO RECOGNISE EEA PRESCRIPTIONS FOR CERTAIN CONTROLLED DRUGS

Response from the Guild of Healthcare Pharmacists

Thank you for the opportunity to respond to this consultation. The Guild of Healthcare Pharmacists represents UK wide around 4,000 pharmacists including the majority of hospital pharmacists, pharmacists employed by Primary Care Trusts (PCTs) and pharmacists employed by other public bodies such as the Commission for Social Care Inspection and the Healthcare Commission. The Guild is part of the health sector of the union Unite.

Our response to main questions regarding the draft standards are as follows:

1. Emergency sale of Schedule 4 or 5 controlled drugs subject to prescription

We agree with the proposal

Our comments on the proposal are:

President: David Miller

Professional Secretary: Barry Corbett

Email: barry_corbett@hotmail.com

Website: www.ghp.org.uk

The current legislation is restrictive, unjustified and disproportionate for the purpose of maintaining public health and safety. Schedules 4 and 5 controlled drugs (CDs) that are available to UK nationals as prescription only medicines should also be available to EEA/Swiss nationals on the presentation of a valid EEA prescription so long as the pharmacist uses his/her professional judgement on whether to dispense a prescription but he/she should be under no compulsion to do so if they have concerns about the authenticity of the prescriber or they consider supply to be unsafe. A pharmacist should be able to make an emergency sale of a schedule 4 or 5 drug, where these are subject to prescription, on the same conditions as set out in the POM Order, so long as the pharmacist adheres to the main requirements of this Order.

The more stringent management of controlled drugs (CDs) following the Shipman Inquiry and the greater awareness by pharmacists of the necessary controls and safety issues, particularly for schedule 2 and 3 CDs, should indicate that the proposed amendment should not pose problems or challenges for pharmacists. However, we do have concerns regarding schedule 4 and 5 CDs, which form a relatively large number of medicines, prescribed. Although (a) the Care Quality Commission's third annual report (following the Shipman Inquiry and implementation of the amended regulations on CDs) stated that systems and services are continually being developed to manage CDs more effectively, and noted the progress made in embedding the systems and processes necessary to support health professionals in managing CDs and to pick up concerns, and (b) the increased CD monitoring and inspection visits are conducted as part of routine pharmacy visits, which highlight any deficiencies or concerns in relation to the supervision of management and use of CDs and provide valuable practice guidance and advice to community pharmacists to ensure compliance, we feel that this increased diligence post Shipman may not necessarily translate to schedule 4 & 5 CDs. We therefore propose that the change in the regulations must be sufficiently robust to identify and prevent Shipman-type incidents by including suitable arrangements for (a) 'increased awareness of the new regulations' with respect to the systems developed for managing CDs post Shipman Inquiry; this will have implications for staff training, locum pharmacists, increased monitoring, maintaining records of concerns, sharing information, and (b) 'increasing quality and frequency of the inspections' with respect to schedule 4 and 5 CDs.

2. Emergency sale of Phenobarbitone or Phenobarbitone sodium (now Phenobarbital or Phenobarbital sodium) for the treatment of epilepsy

We agree with the proposal

Our comments are:

There should be an exception to the continuing exclusion of schedules 1-3 controlled drugs for the emergency sale by UK pharmacists for the treatment of epilepsy particularly as epilepsy can be life threatening and so the best interests of the patient should be uppermost, provided that the following requirements are fulfilled - (a) the request is from an EEA prescriber or, where the request originates from a patient or patient representative, verifiable evidence is available that an EEA prescriber has previously prescribed Phenobarbitone or Phenobarbitone sodium for the treatment of epilepsy, (b) all of the requirements of the current POM Order are fulfilled, and (c) the final decision whether or not to make an emergency sale rests with the professional judgment of the pharmacist.

3. Professional Guidance

Our suggestions on the expansion of the scope and content of the professional guidance are:

1. When dispensing of EEA prescriptions for schedule 4 and 5 controlled drug the pharmacist must exercise due diligence satisfy themselves that:

(a) the prescription is not fraudulent

- contact a registering body of doctors or dentists in another EEA country in order to obtain the prescriber's contact details. (The General Medical Council (GMC) has a document on its website which details the contact details for the equivalent competent authority within the EEA, and The

General Dental Council (GDC) also has a useful document on its website which contains the contact details for the equivalent competent authorities within the EEA)

(b) the prescription meets the requirements of the Regulations

(c) the prescription is clinically appropriate for the patient

2. In the case of an emergency supply that:

- The request of the doctor/ dentist is genuine
- The request of the patient is genuine

3. The pharmacist retains the right not to dispense the prescription or to make an emergency supply if he/she has any concerns. However, the pharmacist must consider the consequences of not dispensing the prescription or making an emergency supply. Pharmacists must exercise their professional judgement, and record the reason why the decision was made not to dispense or supply the medicine (e.g. the pharmacist is not able to contact the prescriber or the pharmacist was not satisfied the patient was previously prescribed the medication). If in any doubt about what is being prescribed the pharmacist must exercise caution. Any decision must be made in the best interests of the patient.

4. Suggestions for handling potential impact in Northern Ireland are:

We have no comments on this issue.

5. Impact of Legislation on Business

We have no comment on any additional direct or indirect costs (recurring and non-recurring) arising from this consultation.

6. Equality Impact

We have no comment on the specific equality issues listed in the consultation.

We hope these comments are of assistance

Our reply may be made freely available.

Yours faithfully

Barry Corbett
Professional Secretary
Guild of Healthcare Pharmacists

Graeme Richardson
Chair of Practice
Guild of Healthcare Pharmacists