RPSGB Response to Proposed Changes to the Misuse of Drugs Regulations 2001 and the Misuse of Drugs Regulations (Northern Ireland)

The Royal Pharmaceutical Society of Great Britain (RPSGB) is the professional and regulatory body for pharmacists in England, Scotland and Wales. It also regulates pharmacy technicians on a voluntary basis, a role that is expected to become statutory under new legislation soon. The primary objectives of the RPSGB are to lead, regulate, develop and represent the profession of pharmacy.

The RPSGB has the following views on the issues raised in the consultation letter.

A. Re-schedule of Midazolam from Schedule 4 to Schedule 3 of the Regulations
The RPSGB supports the rescheduling of midazolam from Schedule 4 to Schedule 3 of the Regulations. To ensure that patient care is not compromised when rescheduling midazolam, all healthcare professionals will need to be made aware of the implications of the change in Schedule, particularly the change in prescription requirements. The RPSGB believes that the implementation date for these changes must allow a sufficient transitional period to raise awareness of the changing requirements and enable necessary guidance to be provided for healthcare professionals. The RPSGB notes that the requirements outlined below for requisitions would apply to midazolam should it be re-scheduled.

The RPSGB supports the intention to continue to allow midazolam to be supplied or administered under a Patient Group Direction (PGD). PGDs have an important role to play in enabling patients to access the medicines they require in a timely manner when there is no independent prescriber present. The statutory requirements for PGDs are tightly drawn and the process for developing and implementing PGDs within organisations are strictly controlled to safeguard patient care and minimise the risk of drugs being inappropriately diverted. The RPSGB cannot envisage patient safety concerns by continuing to allow midazolam to be supplied or administered under a PGD.

The RPSGB supports the view that midazolam should be exempted from the Safe Custody Regulations due to the pressure on storage space for CDs together with the fact that, based on current experience, the risk of diversion is low.

B (1) Audit trail: Requisitions for Schedule 1- 3 CDs in the community
The RPSGB supports the proposed changes to enable a verifiable audit trail for CDs supplied to healthcare professionals for stock purposes. The proposals for requisitions to be sent to the Prescription Pricing Division (or equivalent) will enable monitoring of supplies of CDs to healthcare professionals and is important for both patient and public safety.

However, whilst these changes will enable data about the recipient of the CD stock to be centrally collated, the RPSGB would like to highlight that that these changes do not provide for the monitoring of the legal content of the requisitions. As monitoring and inspection agencies, such as the RPSGB Inspectorate, will no longer see these requisitions during inspection visits (other than any requisitions that may be awaiting submission to the PPD or equivalent that month), failure to comply with requirements such as stating the ‘purpose for which the drug is required’ will not be routinely picked up.

In addition, the RPSGB has concerns as to how the PPD (or equivalent) will monitor the content of the requisitions effectively where no standardised form is in use. The Society recommends the use of standardised forms, with serial numbers, to obtain

controlled drug stock for surgery use, as well as stock obtained by others e.g. midwives, persons in charge of laboratories concerned with scientific education or research. The use of serial numbers on standardised forms will increase traceability and control over requisitions and will need to ensure that requisitions are not lost in the system.

Consideration also needs to be given to whether there will be a legal requirement for the PPD (or equivalent) to retain the requisition forms for a specified period of time (for example, 2 years). If there is no such requirement dealing with problems about supplies of CDs made against a requisition may be difficult in the absence of original documentation.

The current Regulations do not require pharmacists to issue a written requisition to wholesalers in order to obtain stocks of CDs. Controlled drug stock is generally ordered electronically by pharmacists in the same way as other stocks. Because of the volume of controlled drug stock ordered and the need to have same day/next day delivery, any requirements for pharmacists to use a written form when ordering controlled drug stock would be impractical and would not be in the patient's best interests.

The RPSGB questions the need to include the name and address of the supplier on each requisition as the requisitions would presumably be sent to the PPD (or equivalent) with the prescriptions the pharmacy has dispensed at the end of each month. Information about the name and address of the supplying pharmacy is provided at this time. The pharmacy is also required to maintain records of all supplies of CDs and other prescription only medicines supplied against a requisition. Additionally there is no equivalent requirement for private Schedule 2 and 3 controlled drugs to be marked with the name and address of the supplier. Should the name and address of the supplier need to be added to the requisitions the RPSGB would not envisage that this would need to be in the supplier's handwriting.

The proposal states that the requirement to add the supplier information would include both private and NHS requisitions, however there is currently no difference between an NHS and non-NHS requisition within the Regulations. The Regulations should not begin to differentiate between requisitions as this would lead to confusion.

Clarification is also requested around the statement that 'only those who currently return prescription forms to the PPD (or equivalent) will be required to submit requisitions'. Community pharmacies that do not have a contract to dispense NHS prescriptions would not return prescriptions forms to the PPD (or equivalent) unless the prescription was a private prescription for a Schedule 2 or 3 controlled drug. However, these pharmacies may be presented with a requisition for a controlled drug and we believe that there should be a clear requirement for all registered retail pharmacies to submit requisitions. Additionally, the majority of dispensing doctors obtain stock directly from wholesalers. Currently wholesalers do not submit information to the PPD or equivalent. This means that the majority of requisitions issued by dispensing doctors would not be submitted to the PPD for central monitoring and analysis under the new arrangements. The Society believes that this leaves a large gap in the audit trail and presents possible risks.

B (2) To allow accountable officers to authorise a person or a class of persons to witness destruction of CDs.

The RPSGB agrees accountable officers should be provided with the ability to authorise a person or a class of persons to witness the destruction of CDs. The RPSGB supports the recommendation that this provision should sit side by side with

the current arrangements and believes that the interim measure to expand the groups to include any officer of a healthcare organisation who is directly accountable to an executive officer of the organisation should continue following the changes in legislation.

The Society's inspectorate reports large problems with the accumulation of obsolete stock Controlled Drugs awaiting witnessed destruction in community pharmacies. Currently there are limited numbers of authorised witnesses available at a local level to undertake this task, which is contributing to the problem. The Society is concerned about the potential security risks associated with pharmacies holding unnecessarily large stocks of Controlled Drugs and it is the Society's view that the legislation should be brought into force as soon as possible to enable accountable officers to authorise a person or class of persons to witness destruction of Controlled Drugs.

Any delay in implementation will cause an exacerbation of the current problems. Accountable Officers will need to be provided with appropriate guidance to enable them to carry out this task as soon as the legislative provisions are in place.

With the increase in the number of persons authorised to destroy CDs, the RPSGB would welcome a strengthening of the Regulations to require the person witnessing the destruction to record in the controlled drug register their name, professional registration number, where relevant, and the authority under which they are operating. Currently the requirement is only for a signature of the authorised witness to be recorded, together with the date of destruction and quantity destroyed.

The RPSGB would seek clarification as to whether the authorised person can witness destruction in any locality or whether they will be restricted to the area for which the accountable officer has authority, and whether a person would remain authorised should the accountable officer resign or move. The RPSGB would also wish to clarify if there is to be a limit on the number of persons who can be authorised, for how long the authorisation will last and whether they will have any documentation to show they are authorised to witness destruction. Finally, the RPSGB would seek clarity on whether it is the person, or their role, that will be authorised.

The RPSGB notes that the accountable officer must document any authority they provide and must set out any terms that are to be applied to that authority. The RPSGB would seek clarification as to whether the terms of the authority (potentially including the areas outlined in the preceding paragraph) will be in the content of the Regulations, or in good practice guidance.

It is important to note that accountable officer legislation is not yet in place in Wales. The RPSGB understands that the provisional date for the legislation in Wales is October 2007.

C To allow Operating Department Practitioners (ODP) to possess ad supply CDs in a hospital operating department (theatre); to replace the term Sister or Acting Sister with Senior Registered Nurse or Acting Senior Registered Nurse and to……under a clinical management plan.

The RPSGB supports the recommendation to allow ODP to possess and supply CDs in a theatre. We support this recommendation on the basis that ODP are now registered with and regulated by the Health Professions Council (HPC). The RPSGB believes that only those ODP who are registered with the HPC and who have undergone adequate and relevant training should possess and supply CDs in a theatre.

The RPSGB also supports the recommendation to replace the term Sister or Acting Sister with Senior Registered Nurse or Acting Senior Registered Nurse and welcome this move to update legislative terminology in line with changes in practice.

The RPSGB strongly recommends that references to independent prescribers should include pharmacist independent prescribers. Whilst pharmacist independent prescribers cannot currently prescribe CDs it is anticipated, subject to the outcomes of a recent consultation that this will change in the future. It is important this proposed amendment will not require further re-wording in a few months' time.

D To remove the prescribed form of the CD register (CDR) set out in Schedule 6 of the Regulations and replace it with a requirement to maintain designated fields of information in the CDR under specified headings

The RPSGB welcomes the decision to update the terminology used in the text of the Regulations, particularly with regards to the amount received and supplied, which is understood to be the number of dosage units. We believe that specifying the fields of information to be recorded, but not the format that the register must take, will provided the necessary flexibility whilst still ensuring the consistency of information recorded and enabling effective monitoring of recording keeping requirements.

The proposed requirement to have separate register pages for each strength and form of individual drug will help to improve the ease with which a running balance will be maintained. The RPSGB would however note that this format will not allow ready identification of dose alteration or patients who are prescribed a combination of strengths of the same drug.

E To amend the Misuse of Drugs (Safe Custody) Regulations 1973 and the Misuse of Drugs (Safe Custody) Regulations (Northern Ireland) Regulations 1973 to include care homes

The RPSGB supports the recommendation for the above legislation to be amended to include care homes. This change will bring the Safe Custody regulations into line with the amendments made due to the Care Standards Act 2000. It is important that care homes are subject to the same requirements as other persons in respect of safe custody and record keeping to ensure the safe and effective use of CDs in this environment.

It is the RPSGB's understanding that in Scotland, the national care standards do not currently require the same level of CD storage as the national minimum standards in the rest of the UK. Therefore the RPSGB believes that the implementation date for these changes must allow a sufficient transitional period to allow care homes in Scotland to have appropriate storage facilities in place.

The RPSGB recommends that the Misuse of Drugs Regulations is also amended at this time to include care homes.

Additional Comments

1. Prescriptions for CDs to be written and transmitted electronically, signed with an advanced signature.

The RPSGB supports this recommendation, but only at such time that systems are sufficiently secure. The electronic transfer of prescriptions for non-CD items is not currently widespread. Therefore, until such time that it is CD prescriptions should continue to be paper based.

When robust systems are in place, the RPSGB would welcome the move to the electronic transfer of prescriptions with an advanced electronic signature. The RPSGB would anticipate that the wording used in the Regulations would mirror the wording currently used in the Prescription Only Medicines (Human Use) Order 1997. NHS regulations would also need to be amended accordingly.

2. Regulatory Impact Assessment

The RPSGB is concerned with the statement:

the professional regulatory bodies have overall responsibility to deal with enforcement issues.

Professional regulators are not enforcement authorities under the Misuse of Drugs legislation and responsibility for criminal enforcement still lies with the police.

3. EU Practitioners

There is a need for clarity around the position of prescriptions written by EU practitioners. The recent EC Reasoned Opinion is under consideration by the Government and may affect the type of controls that the Government can place on prescriptions written by EU practitioners. This RPSGB would wish careful consideration to be given to the potential implications for CDs.