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Dear Chris

Re: Public Consultation- Proposed Changes to Misuse of Drugs Legislation

I am writing on behalf of the Royal Pharmaceutical Society of Great Britain in response to the above consultation document. Please find enclosed our comments with this letter, which we are happy for you to share with others.

If you require any further information or would like to discuss any of the issues with us, please do not hesitate to contact me.

Yours sincerely

Lynsey Balmer

Head of Professional Ethics

The Royal Pharmaceutical Society of Great Britain

Response to the consultation letter - Proposed Changes to Misuse of Drugs Legislation

Introduction

The Royal Pharmaceutical Society of Great Britain (RPSGB) welcomes the opportunity to respond to this consultation. The RPSGB supports action to improve the management of controlled drug use and strengthen the safeguards that prevent poor practice and minimise patient risk. Strengthened controls must however be balanced with the need to ensure that patients can readily access controlled drugs that are necessary for their clinical care.

It is important that the requirements of the Misuse of Drugs Regulations to apply to all health professionals who handle controls drugs and that equivalent controls and monitoring arrangements exist for both the NHS and private sector. However, the differing healthcare environments in which controlled drugs are stored, supplied or administered must be taken into account in any new arrangements.

Simplifying the existing schedules of controlled drugs would help to reduce the current complex storage, record keeping and prescription requirements and provide an opportunity to ensure that tighter controls are in place for those controlled drugs which are most harmful when misused, without extending such requirements to drugs which pose a lower risk. This would be an important step in balancing the need to strengthen safeguards with the need to ensure that patient care and the legitimate use of controlled drugs by healthcare professionals is not compromised.

Similarly, the proposals for repeat prescribing of controlled drugs, non-medical prescribing, supply and administration of controlled drugs and the ability to alter controlled drug prescriptions that have a technical error, would each help to improve patient access to controlled drugs while still ensuring appropriate controls are in place.

Any changes to the Misuse of Drugs legislation must be supported by comprehensive guidance for health professionals to ensure that they are aware of the new requirements and are not deterred from prescribing, supplying or administering controlled drugs that patients require in a safe and timely manner. It will be equally important that patients are made aware of the new requirements, particularly with respect to restrictions on the validity of controlled drug prescriptions and any requirement to present identification when obtaining controlled drugs.

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

Repeat Prescribing of Controlled Drug

It is currently possible for schedule 4 and 5 controlled drugs to be prescribed on a repeat basis, either privately or under NHS dispensing arrangements. The RPSGB would support moves to allow repeat prescriptions for all controlled drugs, provided appropriate safeguards are in place. This proposal would help to control the volume of CDs in the community and help ensure that proposed restrictions on the validity and quantity of controlled drugs prescribed do not inhibit patient care.

The current NHS repeat dispensing arrangements contain a number of checks and balances to guard against inappropriate use or diversion of controlled drugs. The

prescriber has to determine whether repeat dispensing is clinically appropriate in the first instance. The pharmacist then has to assess the appropriateness of the continued use of the drug before each repeat dispensing and be satisfied that there are no other reasons why the repeat prescription should not be dispensed. However, to ensure patient protection, the RPSGB would recommend that certain limitations on the repeat dispensing of schedule 2 and 3 controlled drugs are considered.

The NHS repeat dispensing arrangements in England and Wales require that repeatable prescriptions must be presented to a pharmacy within 6 months of being generated and prescriptions are valid for up to one year from the date of issue. As it is proposed that the maximum validity of prescriptions for schedule 2,3 and 4 drugs should be limited to 28 days, the RPSGB would suggest that repeat dispensing arrangements for schedule 2, 3 and 4 controlled drugs should similarly require that the repeatable prescription be presented to the pharmacy within 28 days of the date of issue. The RPSGB would also suggest limiting the validity of repeat prescriptions for schedule 2 and 3 controlled drugs to three months. We believe that this would provide a suitable balance between having appropriate safeguards in place and enabling patients with long term conditions to readily access the controlled drugs necessary for their clinical care.

Under current NHS arrangements, unless the prescriber specifies the interval between repeat supplies, pharmacists can use their professional judgement to determine the dispensing interval (e.g. they may decide to supply two repeat installments to cover a patient's holiday). The RPSGB recommends that the same arrangements should apply to repeat prescriptions for controlled drugs.

Repeat dispensing is unlikely to be appropriate for all controlled drugs. However, it is recommended that the decision on which controlled drugs should be prescribed on a repeat basis is a matter for professional judgement and should not be enshrined in legislation. The decision on whether a controlled drug should be prescribed on a repeatable prescription will depend on a number of variables, including the condition being treated and the personal circumstances of the patient. Furthermore, a legislative list of drugs or clinical conditions for which repeat dispensing should not be permitted is likely to be difficult to maintain or enforce. The RPSGB recommends that instead, professional guidance and local protocols should be developed to advise on best practice and help ensure broad consistency of arrangements.

Consideration should also be given to whether repeat dispensing arrangements should extend to installment prescriptions for the treatment of drug misuse. Again, the RPSGB would suggest that it is likely to be a matter for professional judgment as to whether repeat prescribing is appropriate for the individual circumstances. The validity of such prescriptions may need tighter limitations, but the RPSGB believes that provided robust systems are in place, repeatable prescriptions for the treatment of drug misuse could be beneficial.

It will be important that the same requirements apply to both private and NHS repeat prescribing.

Schedules of Controlled Drugs

The RPSGB believes that streamlining the current schedules of the Misuse of Drugs Regulations would reduce the level confusion that exists around issues such as storage, record keeping and prescription requirements. Much of the current complexity arises from the number of exceptions to the requirements of each schedule. Simplification should result in standardised requirements for all drugs

within a particular schedule. An assessment of the safety and risk potential of each drug would help to ensure that tighter controls are in place and more detailed records are kept for those controlled drugs which are most harmful when misused, without extending such requirements to drugs that pose a lower risk. This would help balance the need to have appropriate controls in place to safeguard patients and prevent diversion of controlled drugs with the need to ensure patients are able to obtain drugs necessary for their clinical care and the desire to minimise additional burdens on frontline staff.

The RPSGB would however have concerns if any reduction in the number of schedules unnecessarily increased regulation and would welcome the opportunity to contribute to future discussions about how the schedules could be simplified.

Other proposed measures and regulatory impact assessment

Maximum validity of prescriptions

The RPSGB supports proposals to restrict the validity of prescriptions for schedule 2, 3 and 4 controlled drugs to 28 days. Limiting the validity of controlled drug prescriptions, together with proposals for professional guidance that single prescriptions for controlled drugs should normally be limited to 28 or 30 days' supply, will reduce the potential for controlled drugs being dispensed beyond their clinical need or being inappropriately stored or diverted. Repeat dispensing arrangements for controlled drugs would help ensure that any restriction on prescription validity does not impact on patient care.

To ensure patient care is not compromised, the RPSGB recommends that patients should be advised of the expiry date of their controlled drug prescription and where appropriate, how a new prescription can be obtained. The inclusion of the phrase *'This prescription is valid until…..'* would help ensure patients are aware of the time frame in which the prescription must be dispensed.

With regard to continuity of care for patients in chronic or intermittent recurring pain, the RPSGB recommends the ability to issue a controlled drug prescription in advance of its start date, provided the start date and expiry date (i.e. date before and after which it could not be dispensed) are clearly stated.

Good practice guidance to support this should be developed for prescribers, dispensers and patients.

Non-medical Prescribing, Supply and Administration

The RPSGB believes that supplementary and independent non-medical prescribing play a valuable role in patient care and supports proposals for chiropodists/podiatrists, physiotherapists, radiographers and optometrists who are supplementary prescribers to prescribe controlled drugs. The requirement for supplementary prescribers to prescribe in accordance with a clinical management plan that is agreed with the independent prescriber and the patient, together with the requirement for the clinical management plan to state the class or description of medicinal product that can be prescribed and the conditions which may be treated, will provide safeguards against inappropriate supplementary prescribing of controlled drugs.

As with all prescribers, it will be important that Allied Health Professionals who are supplementary prescribers only prescribe CDs within the limits of their professional expertise and competence. Training programmes should encompass the legal and professional requirements of controlled drug prescribing, supply and administration and the relevant professional regulatory bodies should be asked to produce guidance

on the professional obligations of controlled drug prescribing detailed in *Safer Management of Controlled Drugs*. Similarly all health professionals who prescribe, supply or administer controlled drugs should be required to inform their regulatory body and employer/primary care organisation of any caution or conviction or disciplinary action taken by a regulator in relation to controlled drug issues. Any restrictions of a health professional's prescribing rights must be promptly made available to those who need to know, especially pharmacists. To ensure public protection, the relevant regulatory bodies must have the necessary powers to remove a health professional's right to prescribe, administer or supply controlled drugs where necessary.

Patient group directions (PGDs) also play an important role in improving the quality of patient care by providing ready access to suitable treatment within the NHS and private sector. The RPSGB believes that it is important to safeguard the current and future arrangements for the supply and administration of medicines in accordance with a PGD and supports proposals to expand the current arrangements to include occupational therapists, prosthetists and orthotists. PGDs provide a robust framework and verifiable audit trail for the supply and administration of medicines. This, together with the restricted circumstances in which controlled drugs may be supplied under a PGD that are detailed in the Misuse of Drugs legislation, should ensure appropriate safeguards are in place to protect patients while making it easier for patients to access the controlled drugs they require.

Proposals to facilitate monitoring/analysis of controlled drug prescribing
While the consultation letter does not explicitly stipulate which schedules of controlled drugs these proposals will apply to, Regulation 15 of the 2001 regulations applies to all controlled drug prescriptions except those for schedule 4 and 5 controlled drugs and temazepam. The RPSGB therefore assumes that it is intended that the above proposals will have the same application, but would recommend that these be reviewed as part of any rescheduling exercise to ensure that any additional controls are restricted to those controlled drugs which are most harmful when misused.

The RPSGB supports proposals to require prescriptions for controlled drugs, including private prescriptions, to carry an identification number unique to the prescriber and would suggest that this number should be the prescriber's professional registration number. In theory this will enable accurate attribution of prescriptions to the authorising prescriber, permit more accurate auditing and monitoring of prescribing habits and assist identification of abnormal prescribing. It will also aid pharmacists in their record keeping requirements for controlled drugs. However, it is important to recognise the potential limitations of this requirement. In some instances (e.g. repeat prescribing where a prescription is automatically generated), the identification number printed on the prescription will be that of the prescriber who initiated the treatment, but not necessarily that of the prescriber who signed the prescription. This issue will need to be clarified if accurate audit trails are to be maintained.

A prescriber's failure to enter his unique identification number should not automatically invalidate the prescriptions where the pharmacist judges this to be a technical breach. The pharmacist would need to confirm the prescriber's identification number retrospectively in order to comply with subsequent proposals for controlled drug register records, but the RPSGB recommends that pharmacists should be permitted to add the missing details without returning the prescription to the prescriber. A prescriber's failure to include their identification number on controlled

drug prescriptions should be monitored by the PPA, or similar body, and appropriate action taken if there is persistent failure to comply.

Similarly, the RPSGB supports the proposal for any prescription for controlled drugs, including private prescriptions, to carry a unique patient identifier. Failure to include this number should not invalidate the prescription if the pharmacist judges this to be a technical omission. A code of practice or guidance on access to and use of confidential personal information in relation to this requirement, as proposed in the consultation letter, will be extremely important. Further guidance will also be required on the obligations of prescribers and dispensers who are faced with patients that are unable or unwilling to supply their NHS number. For example, private prescriptions may be written for patients who are not registered with the NHS and therefore do not have a NHS number (e.g. overseas patients). The RPSGB would not wish to see patients deprived of essential treatment in these circumstances and recommends that there must be provision to prescribe and supply controlled drugs when patients do not have a NHS number, or the patient's NHS number is not known.

The RPSGB welcomes proposals to require non-NHS prescribers to use standard controlled drug prescription forms. These forms should be based on the current format of NHS prescriptions, but distinct enough to prevent confusion. Any legislative changes with regard to prescription forms should not impede the current arrangements for prescribing controlled drugs in hospitals and similar institutions.

Standardisation of private prescription forms will not by itself increase the level of control sufficiently. This can only be achieved if private and NHS controlled drug prescription forms are monitored collectively. The RPSGB agrees that all controlled drug prescriptions should be submitted for analysis and reconciliation by the PPA, or equivalent organisation, after the controlled drugs have been dispensed. As pharmacists are currently required to keep all private prescriptions for two years from the date of last supply changes to Medicines Act legislation will be required to implement this change. Inspection and monitoring arrangements will also need to clearly identify who is responsible for analysing private prescription data and provide systems to ensure that any concerns are appropriately investigated.

Mandate the use of standard forms for any requisition of controlled drugs and submission of these forms to the PPA

The RPSGB believes that introduction of standardised requisition forms for controlled drugs stock and the subsequent submission of these forms to the PPA, or other appropriate body, is necessary for comprehensive auditing and monitoring of controlled drugs. Inspection and monitoring arrangements should identify who will be responsible for analysing requisition data and include systems to ensure that any potential problems or concerns are further investigated.

For ease of monitoring it may be advisable to separate the forms used to order stocks of controlled drugs from requisitions of other medication. Consideration should also be given to the potential for electronic transfer of requisitions once robust secure systems are in place. Again the consultation letter does not explicitly state the schedules of controlled drugs that these proposals will apply to. As the current requisition requirements do not extend to schedule 4 and 5 controlled drugs, the RPSGB assumes that these schedules of controlled drugs will also be exempt from any new requisition requirements, but would further reiterate its support for a fundamental review of the scheduling arrangements to simplify the current complex requirements.

The RPSGB also supports the proposal to focus this requirement on requisitions from GP practices, out of hours services and other settings where controlled drugs are administered to patients. We would however wish to ensure that the phrase 'and other settings where controlled drugs are prescribed to patients' will capture practitioners writing signed orders for private healthcare, including those issued by dentists and vets. In time this requirement should be extended to others authorised to obtain stocks of controlled drugs e.g. persons in charge of laboratories concerned with scientific education or research, owners/masters of ships and managers of offshore installations.

The current Misuse of Drugs Regulations do not require pharmacists to issue a written requisition in order to obtain stocks of controlled drugs. In community and hospital practice pharmacists generally order controlled drug stock electronically from wholesalers in the same way as other stocks of medicines. The volumes of controlled drug stock ordered and the need to have same day/ next day delivery means that any requirement for pharmacists to use a written form when ordering controlled drug stock would be impractical and, in many instances, would not be in the patient's best interests. The RPSGB believes that monitoring of wholesaler dealers' records, the requirement for running balances of controlled drugs in pharmacies and the keeping of pharmacy records provide robust monitoring of pharmacy controlled drug stock. Any additional requirement to use a written requisition form would place an unnecessary additional administrative burden on pharmacists.

The RPSGB recommends robust arrangements be made to ensure that controlled drug stock from wholesalers is delivered to an authorised person. Formal records should help complete the audit trail and reduce the risk of diversion of stock.

Healthcare providers to have standards operating procedures if they hold stocks of controlled drugs on their premises

The RPSGB supports plans to introduce a requirement for all healthcare providers holding stocks of controlled drugs to have and comply with the terms of an agreed Standard Operating Procedure (SOP). Inspection and monitoring systems will need to monitor adherence to this requirement. While there is a need for broad consistency, it will be important that SOPs have sufficient flexibility to take account of local circumstances and the different environments in which controlled drugs are stored, supplied or administered. The RPSGB would wish to be involved in the development of any supporting guidance.

Record keeping and registers

The RPSGB welcomes the proposed amendments to Regulations 19 and 20 of the 2001 Regulations for record keeping and controlled drug registers to make clear that controlled drugs registers may include running balances of stock and that the current regulations merely specify the minimum requirements for controlled drug registers. The RPSGB has issued best practice guidance to encourage pharmacists to maintain running balances of controlled drug stock and believes that the ability to maintain electronic CD registers will be an important step in supporting this requirement.

The RPSGB recommends that when running balances become a legal requirement, there should not be a strict liability offence in the event of difficulty with reconciliation when there is a justifiable reason for the discrepancy. This is to take account of the fact that unavoidable discrepancies will arise between the actual balance and theoretical balance as a result of, for example, the viscosity of certain liquids and manufacturer's overage.

The RPSGB also supports proposals to allow the name and identification number of the prescriber and dispenser to be recorded in the controlled drug register. We recommend that the prescriber's identification number recorded in the controlled drug register should be the same unique identification number that will be required to appear on controlled drug prescriptions. As previously indicated, consideration needs to be given to situations where CD prescriptions bear the reference number of the prescriber who initiated the prescription rather than the prescriber signing it (e.g. repeat prescriptions). This matter will need to be addressed in order to enable pharmacists to comply with the proposal and ensure accurate audit trails are maintained.

With regard to the recording of the dispenser's details, it is important to recognise that the pharmacist who supervises the assembly of a patient's medication may not be the same pharmacist who supervises the supply of the controlled drug to the patient. It is the RPSGB view that it is the pharmacist who supervises the supply of a controlled drug to a patient, or their representative, rather than the pharmacist who is involved in the assembly process, whose details should be entered in the register. The RPSGB's Code of Ethics requires that a retrievable record of the pharmacist taking responsibility for the provision of each pharmacy service be maintained. Thus, a system for recording the responsible pharmacist at the time of assembly and the pharmacist at the time of supply should be in operation. The RPSGB will provide further practice guidance to support this requirement in order to help ensure an audit trail is maintained.

Dispensers to ask for personal identification from person presenting a prescription for controlled drugs

The RPSGB supports the need to try close the loopholes through which a patient's controlled drugs could be diverted. However the RPSGB continues to express its concern about proposals to require pharmacists to ask for the name, address and some form of identification of patients, or patient's representative, collecting controlled drugs. Special arrangements for the collection of controlled drugs may pose patient confidentiality issues. Many patients rely on friends, relatives, neighbours and home help/carers to collect controlled drugs on their behalf and the patient may not wish their representative to know that they have been prescribed a controlled drug. The RPSGB is also concerned that this proposal could deter individuals who have previously collected medication to assist patients from doing do in the future and result in delays in patient care. Furthermore, there is a risk that this requirement could, in some instances, increase the risk of diversion as representatives will then be aware that a controlled drug has been prescribed.

This proposal must not prevent patient's accessing the medicines they need. It is imperative that pharmacists and other dispensers have the discretion to make a supply when no identification is presented without fear of committing an offence. Legislation should also make clear that any requirement to ask for the name, address and some form of personal identification will only apply when the person is not already known to the dispenser. This will be especially important in ensuring that the provision of daily pharmaceutical services for drug misusers is not compromised. Even with this proviso, the RPSGB foresees that locum pharmacists in particular may still encounter difficulties if a drug misuser presents to collect an instalment supply without identification and it is not possible to verify the patient's identity with other pharmacy staff. Additionally, this requirement will only provide the desired safeguards if dispensers have clear guidance on trigger factors for raising concerns about the potential diversion of controlled drugs.

It is essential that the introduction of such a requirement be supported by a major public awareness campaign to inform patients that they or their representative will be required to confirm their identity when collecting certain controlled drugs and advise on the types of identification that will be acceptable. Prescribers should also inform patients when they have been prescribed a controlled drug to which the identification requirements apply. Consideration could also be given to including such information on the prescription form.

The RPSGB would wish to work with the Home Office and Department of Health to develop guidance around these proposals. In addition to advising on issues around confidentiality and types of acceptable identification, consideration will also need to be given to situations where controlled drugs are delivered to a patient's home by either pharmacy staff or a third party carrier rather than being collected from a community pharmacy (e.g. on-line/mail order pharmacy services).

Identification of healthcare professionals presenting a prescription or requisition for controlled drugs

As stated above, the RPSGB supports the need to try to prevent the diversion of controlled drugs. Specific requirements for the collection of controlled drugs by healthcare professionals are unlikely to pose confidentiality concerns. Therefore, provided steps are taken to ensure healthcare professionals have and routinely carry relevant identification, the RPSGB believes that a requirement to confirm and record the identity of health professionals who collect controlled drugs that have been prescribed for a patient, or ordered against a requisition, could be implemented with relative ease. However, this requirement will only provide the desired safeguards if dispensers have clear guidance on the trigger factors for raising concerns about potential diversion or unlawful supply of controlled drugs.

Proposals to allow pharmacist or dispenser to alter prescriptions where there is a 'technical error' but where the prescribing intention of the prescriber is clear

The RPSGB welcomes proposals to allow pharmacists to alter a prescription and make a supply of controlled drugs in cases where there is a technical error but where the prescribing intention is clear.

In a survey by the RPSGB Inspectorate at the beginning of 2005, 85% of pharmacists reported receiving controlled drug prescriptions with technical errors. The current prescription requirements for Schedule 2 and 3 controlled drugs, together with the need for any alterations to be effected by the original prescriber in his/her handwriting, pose a frequent practical and ethical problem for pharmacists. Pharmacists are faced with a prescription that does not meet the necessary legal requirements, but referring patients back to the prescriber for changes to be effected causes delays to patient care and may result in pharmacists failing to comply with one of their key responsibilities to act in the interests of patients and other members of the public.

Alterations to the Misuse of Drugs Regulations to allow all details on controlled drug prescriptions (except the signature) to be computer generated are likely to help to reduce the number of technical errors on controlled drug prescriptions. However, the ability for pharmacists to amend technical errors is still an important requirement to ensure that patients are able to access the controlled drugs they require without undue delay.

The RPSGB supports the proposed circumstances in which pharmacists would have discretion to amend prescriptions for controlled drugs detailed in Annex C. The

RPSGB believes that these proposals will provide the necessary means for pharmacists to supply controlled drugs where the prescriber's intention is clear, while still providing safeguards to ensure that supplies are not made in circumstances where the authenticity or validity of the prescription may be in doubt. It will be important that prescribers are informed of the technical error at the earliest convenient opportunity and that appropriate records are kept of any amendments made. The RPSGB will produce professional guidance on the action to be taken when pharmacists are presented with a controlled drug prescription that does not comply with the requirements of the Misuse of Drugs Regulations and will publicise this widely to the profession.

An additional problem that pharmacists frequently face that is not specifically addressed in Annex C is where a patient fails to collect an instalment supply of controlled drug on the specified date. This is a particular problem for prescriptions for substance misuse. Where the instalment is intended to cover more that one day's supply pharmacists have no authority to supply the remainder of the instalment (i.e. the instalment less the amount prescribed for the days missed) on a subsequent date. To address this problem, the Home Office recently confirmed that they are content for the following stamp to be used by those prescribing controlled drugs by way of instalment

"Supervised consumption of daily dose on specified days; the remainder of supply to take home. If an instalment prescription covers more than one day and is not collected on the specified day, the total amount prescribed less the amount prescribed for the day(s) missed may be supplied."

Use of this stamp enables those supplying controlled drugs to issue the remainder of the instalment prescription where a person fails to collect their supply on the specified day. However, the RPSGB propose that pharmacists should have the discretion to issue the remainder of the instalment in circumstances where the above wording does not appear on the prescription. Pharmacists would be required to use their professional judgement to decide whether making the supply, less the days missed, would be appropriate and would need to take into consideration the possibility that the patient may have used other illegal substances in the interim period. Consideration would also need to be given to whether it may be appropriate to contact the prescriber before the supply is made. This is area where the RPSGB could issue further guidance. The guidance could advise that the prescriber be informed if the patient fails to collect the supply on specified days. This would assist the prescriber monitor patient compliance and allow an informed judgement to be made on future treatment patterns.

Witnessing destruction of controlled drugs

The RPSGB recommends that appropriate systems should be in place to witness and record the destruction of both surplus controlled drug stock and patient returns and believes that consistent legislative requirements should exist for this.

The RPSGB welcomes proposals to broaden the groups of people entitled to witness the destruction of surplus controlled drug stock. The accumulation of out of date/excess controlled drug stock that is awaiting destruction by an authorised witness pose both storage problems and a security risk. This is a particular concern for community pharmacies. In a survey conducted by the RPSGB Inspectorate, there was evidence of pharmacists stockpiling old or obsolete controlled drugs awaiting destruction. This situation is likely to be exacerbated when Police Chemist Inspection Officers discontinue routine visits to pharmacies as the survey showed that 79% of controlled drug destructions in pharmacies were being undertaken by CIOs at that

time. With regard to the destruction of controlled drugs returned from patients, the RPSGB currently advises that the destruction of such drugs by pharmacists should be witnessed by a second person (e.g. another member of staff) and that a record be made of this. The RPSGB would support a legislative requirement to this effect.

Both the witness and the person carrying out the destruction should be professionally accountable for their actions. When determining the categories of people who might appropriately witness destruction of controlled drugs, it will be important to take a pragmatic approach to ensure that the list is not too restrictive, especially in light of proposals to encourage patients, their representatives and other healthcare professionals to return any unused controlled drugs to community pharmacies for destruction. Tightly restricting the categories of person authorised to witness the destruction of patient returns will result in the further accumulation of controlled drugs in community pharmacies, which in itself will pose a security risk.

The RPSGB would recommend that the destruction of both surplus controlled drug stock and patient returned controlled drugs should be carried out and witnessed by appropriately competent and professionally accountable persons. This could be, for example, two pharmacists or a pharmacist and another health professional.

When amending regulation 27 of the 2001 Regulations full consideration will need to be given to the requirements of Waste Management Regulations to ensure that the safe and timely destruction of controlled drugs is not hampered by conflicting legislative requirements.

The RPSGB also supports the proposals to remove the need for exemption certificates authorising the use of alternative CD cabinets to be issued on an annual basis provided the continued appropriateness of these cabinets are considered as part of the new inspection and monitoring arrangements.

Regulatory Impact Assessment

Views have been sought on the Regulatory Impact Assessment (RIA) for 'Safer Management of Controlled Drugs' published in December. Since this RIA was signed off much work has been undertaken to develop the Government's proposals for implementation, especially with regard to the inspection and monitoring arrangements. This should be taken in to account when assessing the impact of the new requirements. Other proposals, in particular those around the use of patient drug records cards and IT are still subject to further scoping work. It is therefore difficult to accurately assess the impact of all the proposals detailed in the Safer Management of Controlled Drugs at this time.

The RPSGB fully supports plans to strengthen the current systems for managing controlled drugs in order to prevent poor practice and ensure that any health professional posing a risk to patient safety is readily identified and appropriate action taken. However, the impact on health professionals, regulatory bodies and other organisations affected by the implementation of the proposals must be proportionate to the benefits gained in terms of public safety. Steps must be taken to minimise additional burdens on frontline staff and ensure that additional safeguards do not compromise the legitimate use of controlled drugs by health professionals or impede patient access to controlled drugs that are necessary for their care.