Department of
Health, Social Services and Public Safety
www.dhsspsni.gov.uk

CONSULTATION

PROPOSED CONSOLIDATION OF THE MISUSE OF DRUGS REGULATIONS (NORTHERN IRELAND) 2002 INCLUDING AMENDMENTS TO SPECIFIC PROVISIONS AND PROPOSALS RELATING TO THE GOVERNMENT'S RESPONSE TO REMAINING SHIPMAN INQUIRY RECOMMENDATIONS.

Closing date for responses: Wednesday 14th December 2011

Introduction

This consultation invites your views on the Department of Health, Social Services and Public Safety's ("the Department") proposals to consolidate the Misuse of Drugs Regulations (Northern Ireland) 2002 (as amended) ("the 2002 Regulations"), and to conduct a review of specific provisions under the 2002 Regulations to ensure that the regulatory framework on controlled drugs is effective, reflects current policy and keeps pace with an ever-changing healthcare landscape, particularly with new healthcare professionals and settings in which care is provided.

The proposals are presented in parallel with the Home Office proposals formulated in discussion with the Advisory Council on the Misuse of Drugs, the independent body established to advise the Government on drug misuse issues.

A response form is at Annex A. Responses should reach the Department by Wednesday 14th December 2011.

Seamus Camplisson
DHSSPS Health Protection Branch
21 September 2011

Objective

1 The objective is to consolidate the 2002 Regulations and make clarifying amendments to existing provisions in order to ensure that the regulations are comprehensive and fit for purpose, and thereby reflect the current policy on controlled drugs available in healthcare and similar settings.

2 These proposals are presented by DHSSPS in parallel with the Home Office. They are aimed at the safe management of controlled drugs in healthcare and the community by bringing into one legislative document the provisions under the 2002 regulations and amending specific provisions where there is a clear and compelling professional and/or policy need.

Options

3 Three options have been identified:

(i) do nothing;

(ii) consolidate the Misuse of Drugs Regulations (Northern Ireland) 2002 (as amended), or

(iii) consolidate the Misuse of Drugs Regulations (Northern Ireland) 2002 (as amended) and amend specific provisions to reflect current policy on controlled drugs.

4 Option (i) would maintain the status quo, meaning the current provisions under the 2002 Regulations would remain as set out in the multiple statutory rules which currently contain provisions under the 2002 Regulations.

5 Option (ii) would consolidate the 2002 Regulations bringing the current provisions under the 2002 Regulations, contained in many statutory rules, into a single legislative document.

6 Since the introduction of the 2002 Regulations on 1st February 2002, there have been many amendments, most of them substantive, to the original statutory rule (Statutory Rule 2002 No. 1) regulations to reflect policy changes and clarify provisions under these Regulations. This has led to the provisions in the 2002 Regulations being fragmented, complex and, in places, difficult to follow.

7 Consolidating the 2002 Regulations will ensure that the regulations continue to be comprehensive and fit for current purpose and reflect current policies in relation to drugs controlled under the Misuse of Drugs Act 1971 ("the 1971 Act") which are also scheduled under the 2002 Regulations. However, this option will not ensure that the provisions under the 2002 Regulations fully reflect current policy on controlled drugs.

8 Option (iii) is the Department's preferred option and therefore the focus of this consultation.

Proposals

9 The following pages set out proposed specific amendments to the 2002 Regulations. For each proposal the Department invites your views on the following questions.

(1) Do you agree with the proposal?

(2) Do you agree with the impact assessment of the proposal?

(3) Are you aware of any further impact on healthcare professionals or institutions and industry as a result of the proposal?

(4) Where a proposal impacts on healthcare professionals, healthcare institutions or the sector, to inform the full impact assessment it will be helpful if you can quantify the burden or savings and the corresponding cash costs or saving per month or year.

Proposal A: AMENDMENT TO EXEMPT HOSPICES AND PRISONS FROM REQUISITION REQUIREMENTS UNDER REGULATION 14(4) AND 14(5) OF THE 2002 REGULATIONS

10 It is proposed to exempt hospices and prisons from the requisition requirements under Regulation 14 of the 2002 Regulations.

11 Hospices and prisons are currently required under the 2002 Regulations to present a Regulation 14 compliant requisition when ordering controlled drugs. Most hospices and prisons have contracts to receive their controlled drug supplies from a community pharmacy or from hospital pharmacies and have historically used duplicate books for their requisitions of controlled drugs.

12 The requirement to present a requisition is not only a cumbersome process for these settings but also is potentially less robust than the previous audited systems. This is because the forms replace the consolidated system of duplicate books previously used by a system based on loose sheets of paper. The use of stock controlled drugs is a routine part of the service of hospices and prisons and so the number of these forms to be managed is seen as an added risk factor.

13 Current methods of data capture using forms make it difficult for any individual practitioner requisition data, within these environments, to be analysed as a result of the significant volume of hospice and prison controlled drug activity. The high volume of controlled drug activity masks the true level of requisition activity of individual practitioners in a given area. The proposed changes would ensure that requisition data provided to the Business Services Organisation and the subsequent analysis are more robust and reflect the original policy intent of capturing requisition activity by individual practitioners.

14 Monitoring of requisition activity within these sectors would fall to Accountable Officers through their oversight of controlled drugs and

therefore requisition activity and the use of Standard Operating Procedures to deal with issues such as retention of duplicate copies following implementation of these proposals. Accountable Officers would have to ensure that appropriate arrangements are in place to provide an effective auditing and monitoring regime for these sectors if and when this exemption comes into operation.

Proposal B: AMENDMENTS TO INCLUDE PARAMEDICS AND OPERATING DEPARTMENT PRACTITIONERS ("ODPs") IN THE LIST OF HEALTHCARE PROFESSIONALS WHO MUST PRESENT A REQUSITION IN ORDER TO OBTAIN CONTROLLED DRUGS FROM A SUPPLIER

15 It is proposed to include paramedics and operating department practitioners in the list of professions required to present a requisition in order to obtain controlled drugs under Regulation 14 of the 2002 Regulations.

16 The 2002 Regulations currently list a number of professionals who need to present a requisition in order to obtain controlled drugs. The provision under the 2002 Regulations enables the capture of data on requisition activity by individual healthcare professionals. Paramedics, engaged by and under the control of the Northern Ireland Ambulance Service Trust, are currently permitted to possess and supply or administer certain controlled drugs under a Department Group Authority issued under the 2002 Regulations or under a Patient Group Direction. Some paramedics work both within the Health Service and in a private capacity. For private purposes they must be individually licensed by the Department to possess and supply or administer certain controlled drugs which they acquire through community pharmacies.

17 Paramedics are currently not required by the Regulations to present a requisition in order to obtain these drugs, although this is recognised as best practice. The proposed changes would put paramedics on a similar footing to other healthcare professionals, ensuring that their requisition

activity can be monitored in line with the overarching aims of the Fourth Report of the Shipman Inquiry on requisitions.

18 ODPs have authority under the 2002 Regulations to possess and supply controlled drugs when acting in that capacity in a hospital. However, ODPs currently do not have explicit authority under the regulations to requisition controlled drugs. The proposed amendments would bring ODPs into line with the other healthcare professionals currently listed under Regulation 14 of the 2002 Regulations, confirming ODPs' authority to requisition the controlled drugs they need when acting in that capacity and within a hospital setting. In addition to enabling ODPs to acquire controlled drugs, the proposals would also place a requirement on ODPs to present a requisition when ordering controlled drugs which would allow the capture and monitoring of individual requisition activity by ODPs within the hospital setting when required.

Proposal C: AMENDMENTS TO EXTEND AUTHORITIES APPLICABLE TO SENIOR REGISTERED NURSES IN CHARGE OF WARDS TO REGISTERED MIDWIFE WARD MANAGERS

19 It is proposed to provide registered midwife ward managers with similar authorities to those currently applicable to senior registered nurses in charge of a ward under Regulations 8, 9, and 10 of the 2002 Regulations.

20 Regulations 8(2)(e) and 9(3)(c) of the 2002 Regulations currently provide authority to senior registered nurses in charge of a ward, when acting in that capacity, to supply or offer to supply controlled drugs to patients in the case of a drug supplied to them by a person responsible for dispensing and supply of medicines in a hospital. Under Regulation 10, senior registered nurses in charge of wards have authority to possess the relevant controlled drugs.

21 Some maternity wards may be managed by registered midwives who do not hold registration as a nurse. This may be because they have undertaken

direct entry training as a midwife and have not trained as a nurse or have terminated their nursing registration as a result of becoming a midwife. This means that under current provisions, the authority for these registered healthcare professionals to possess and supply or offer to supply controlled drugs is absent. The proposed change, if and when implemented, would ensure that registered midwife ward managers have the same authority and responsibility in relation to controlled drugs supplied to them for patients in a maternity ward as already applies to senior registered nurses in charge of a ward.

Proposal D: AMENDMENTS TO MAKE IT A REQUIREMENT TO INCLUDE THE ROYAL COLLEGE OF VETERINARY SURGEONS NUMBER ON PRESCRIPTIONS FOR SCHEDULES 2 AND 3 CONTROLLED DRUGS (EXCEPT TEMAZEPAM)

22 It is proposed to amend Regulation 15(1)(ab) to make it mandatory for veterinary practitioners to include their Royal College of Veterinary Surgeons number on prescriptions for Schedules 2 and 3 controlled drugs except temazepam.

23 One of the key recommendations of the Shipman Inquiry was for private prescriptions for Schedules 2 and 3 controlled drugs in the community to include the prescriber's identification number issued by the Business Services Organisation. This recommendation was implemented for human health care by Regulation 15(1)(ab) of the 2002 Regulations which came into operation on 1 September 2006. Veterinary prescriptions are private prescriptions. However, there is currently no requirement for veterinary practitioners to include a unique identification code when prescribing Schedules 2 and 3 controlled drugs to better enable activity in this sector to be monitored if required. The proposed amendment would bring the veterinary sector into line with human healthcare sector, improving the ability to collate data on individual prescribing activity for the veterinary sector for monitoring when required.

Proposal E: AMENDMENTS TO REMOVE THE REFERENCES TO SCOTLAND FROM REGULATION 14(5) OF THE 2002 REGULATIONS

24 It is proposed to remove the references to Scotland and the National Health Service (Scotland) Act 1978 from Regulation 14(5)(b) of the 2002 Regulations.

25 Regulation 14(5)(b) requires a requisition, furnished for the purposes of obtaining a controlled drug, for stock purposes, by a master of a foreign ship to contain a statement signed by the proper officer of the port health authority within whose jurisdiction the ship is. The current reference to a ship in Scotland does not fulfil any function in the 2002 (Northern Ireland) Regulations.

Proposal F: AMENDMENTS TO CLARIFY THAT REGULATION 15(3) OF THE 2002 REGULATIONS DOES NOT APPLY TO PRISONS

26 It is also proposed to clarify Regulation 15(3) [which enables a prescription for Schedules 2 and 3 controlled drugs for the treatment of a patient in a hospital or nursing home to be written on the patient's bed card] to the effect that it is not applicable to prisons and that a 2002 Regulation compliant prescription needs to be completed.

27 In the absence of specific provisions relating to prisons, provisions under the 2002 Regulations applicable to hospitals and nursing homes could be applied disparately across the sector. As a result, prescriptions for controlled drugs are, in some prisons, written on patient record sheets. There is a huge amount of movement of prisoners between prisons with the effect that on transfer, prisoners are unable to take copies of their prescriptions to ensure they have continuity in their care or treatment. This is more important when prisoners are transferred over the weekend and

therefore have to wait until the following week before they are able to see a practitioner and have a new prescription issued in the receiving prison.

28 This raises serious issues of continuity of care and patient safety. The proposed change will make it mandatory for Schedules 2 and 3 controlled drug prescriptions in prison health care to be written on prescription forms compliant with requirements under the 2002 Regulations which can be transferred with the prisoner to enable continuity in patient care and treatment.

Proposal F: AMENDMENTS TO EXTEND AUTHORITIES APPLICABLE TO SENIOR REGISTERED NURSES IN CHARGE OF WARDS TO SENIOR REGISTERED NURSES IN CHARGE OF PRISON HEALTH CENTRES

29 It is proposed to extend the authorities currently applicable to senior registered nurses in charge of wards to senior registered nurses in charge of prison health centres.

30 Most prisons do not have an on-site pharmacy or a pharmacist on the premises for a significant amount of time. Where there is an on-site pharmacy the pharmacist, having the legal authority to obtain and possess controlled drugs, takes responsibility for controlled drugs management in the pharmacy and for the management around the prison. Where there is no on-site pharmacy, a doctor will be the legally responsible person for signing requisitions etc. Medical services are usually provided with one or more doctors providing sessions in the prison. As a result, there is usually no one person who can take personal responsibility for controlled drugs in a consistent manner. This makes governance arrangements in prisons without a pharmacy less than ideal.

31 The head of health care in a prison is usually a senior registered nurse. Where the head of health care is not a registered healthcare professional,

they will not be able to assume any responsibility for the management of controlled drugs. In prisons with no on-site pharmacy, it is considered that better governance would be enabled if the senior registered nurse, as head of health care, was authorised to possess and supply controlled drugs and as a result made responsible for these drugs within the prison as occurs in the case of a nursing home.

Further proposals – general

32 In addition to proposals A to F above, the Department also proposes to make the following general amendments to the 2002 Regulations and would welcome your comments on these proposals.

Proposal G: INCLUSION OF PRISONS IN THE 2002 REGULATIONS

33 It is proposed to include prisons in the 2002 Regulations to provide clarity on the specific provisions applying to prison health care.

34 There is currently no explicit mention of prisons or prison healthcare units in the 2002 Regulations, although most authorised healthcare professionals working in institutions falling under this description requisition, stock and supply or administer a number of controlled drugs mainly for the treatment of addiction or maintenance of substance misuse. However, the provisions under the 2002 Regulations apply equally to healthcare professionals working in these institutions. This could cause confusion when deciding which provisions specifically apply to this environment and therefore any related exemptions under the 2002 Regulations.

35 The proposed amendments would ensure that specific reference is made to prisons or the prison healthcare units, where needed. This would make provisions applicable to these institutions easily identifiable, and will provide clarity for practitioners and prison healthcare units, ensuring that the

management of controlled drugs within the prison health care is carried out under the terms of the applicable provisions.

Proposal G: MIDWIFE SUPPLY ORDERS

36 It is proposed to amend the 2002 Regulations to make midwife supply orders specific to a patient. References to the legislative arrangements relating to midwives in Regulation 11 will also be updated to reflect current legislation.

37 The Midwives Supply Order was devised in 1985 to ensure that midwives had legal and monitored access to opiate drugs for home birth, using exemptions to administer the drug without prescription. Currently, under Regulation 11 of the 2002 Regulations, a midwife has the authority to possess "any controlled drug which she may, under and in accordance with the provisions of the Medicines Act 1968 lawfully administer" provided the controlled drug has been obtained via a Midwives Supply Order, signed by an "appropriate medical officer" i.e. a doctor or the relevant person appointed to supervise midwives.

38 Owing to a number of concerns regarding the risks of diversion of controlled drugs and to midwives operating in the community, the ACMD has supported the historical proposal by the Nursing and Midwifery Council ("NMC") to update the current arrangements to make the Midwives Supply Order patient-specific, rather than midwife-specific. This will place the Midwife Supply Order on a similar footing to a prescription i.e. when dispensed the controlled drugs become the patient's property and therefore their responsibility, rather than the responsibility of the midwife, thereby removing the risks associated with midwives having to carry controlled drug stock.

Proposal H: AMENDMENTS TO PROVIDE AUTHORITY TO THE NORTHERN IRELAND AMBULANCE SERVICE TRUST TO

POSSESS AND SUPPLY CONTROLLED DRUGS TO PARAMEDICS EMPLOYED BY THE TRUST

39 It is proposed to provide authority, under the 2002 Regulations, to enable the Northern Ireland Ambulance Service Trust ("NIAS") to possess and supply controlled drugs.

40 The current provisions around requisition, supply and possession of controlled drugs by NIAS currently depend upon a controlled drug licence issued by the Department, such as would be issued in the private sector. These arrangements work well and facilitate robust monitoring of NIAS. However, regulations 8, 9 and 10 of the 2002 Regulations currently authorise certain healthcare professionals employed in a particular capacity, within hospitals or nursing home settings, or within hospital wards, theatres and operating departments, to supply and possess controlled drugs. This allows for a robust system to monitor controlled drug use within hospitals and nursing homes.

41 In the absence of a similar authority for the NIAS, the Department uses the Group Authorities provisions and the controlled drug licensing provisions of the 2002 Regulations to enable NIAS paramedics to access the controlled drugs they are permitted to supply or administer under the 2002 Regulations. The proposed changes would provide NIAS with an authority similar to that currently applicable to healthcare professionals employed in a particular capacity in Health and Social Care Trust Hospitals. This would enable NIAS to order, stock and supply drugs to its paramedics without resort to the controlled drug licensing provision. If this provision were then to be used it would facilitate equally robust monitoring and provide a good audit trail for controlled drugs used within this sector.

Proposal J: AMENDMENTS TO ENABLE THE EMERGENCY SALE OR SUPPLY OF PHENOBARBITONE OR PHENOBARBITONE SODIUM (NOW PHENOBARBITAL OR PHENOBARBITAL SODIUM)

42 In August 2010 the Medicines and Healthcare products Regulatory Agency (MHRA) consulted about controlled drugs and EEA prescribers. Responses were supportive including regarding "emergency supplies" of phenobarbital or phenobarbital sodium for the treatment of epilepsy. It is proposed to make any necessary amendments to the 2002 Regulations to enable pharmacists to make "emergency supplies" of phenobarbital or phenobarbital sodium for the treatment of epilepsy. In view of the MHRA consultation, the Home Office and Department have concluded that no further consultation is necessary on this proposal.

Miscellaneous proposals on remaining Shipman inquiry recommendations

43 The Department would also welcome your comments on the following proposals relating to the Shipman Inquiry recommendations.

Requisitions

44 The Home Office is not proposing to introduce a legislative amendment making the use of a standardised requisition form by individual healthcare professionals mandatory at this time. The Department is in agreement with the Home Office that amendment to the 2002 Regulations is not necessary.

45 The Shipman Inquiry recommended in its Fourth Report that the purchase of all stocks of controlled drugs should follow a procedure that is capable of being monitored. The recommendation further highlighted the need for a standardised requisition form, similar to the one used for prescriptions, when individual healthcare professionals requisition controlled drugs, and for the form to be sent to the Business Services Organisation (BSO) so that purchases of controlled drugs by individual healthcare professionals can be monitored. In Northern Ireland the HS21S stock prescription form was already successfully in use and satisfied the Shipman Inquiry recommendations in regard to supplies within the Health Service. Private

stock requisitions by practitioners in Northern Ireland are very rare and in any case are submitted by pharmacies to BSO for monitoring.

Running balances

46 It is proposed not to make running balances for controlled drug registers a mandatory requirement at this time but to review the position in the light of further information.

47 The Shipman Inquiry also recommended in its Fourth Report that the keeping of running balances in controlled drug registers in pharmacies should be regarded as good practice and that when electronic registers have come into wide use, the keeping of running balances should be made obligatory. The use of running balances is currently encouraged as good practice and evidence in Northern Ireland shows that community and Trust pharmacies comply admirably with the good practice guidance.

48 The Home Office and Department are of the view that the use of electronic controlled drug registers has not yet reached an extent that would warrant making running balances obligatory. The situation will be kept under review. Comments support or challenging this view are welcome.

Impact of options

49 A consultation stage impact assessment has been prepared in line with the proposals outlined in the consultation and has been assessed to be negligible. The Department is however interested to hear from the healthcare sector and healthcare professionals where any direct and indirect costs may arise as a result of these proposals.

Equality

50 Section 75 of the Northern Ireland Act 1998 requires each public authority, in carrying out its functions in relation to Northern Ireland, to have due regard to the need to promote equality of opportunity.

51 The changes proposed under this review have been screened for the purposes of the section 75 equality duty and in light of that screening exercise the Department has concluded that a full Equality Impact Assessment of these proposals is not needed.

General provisions

52 The proposed changes to the Misuse of Drugs Regulations 2002 would have effect in Northern Ireland only and would keep parity with GB.

53 Implementation of the proposed changes would take place in April 2012 subject to any comments received in response to this document.

Circulation of proposals and consultation responses

54 A copy of this documents and attachments is also available at: www.dhsspsni.gov.uk/index/consultations/current_consultations.htm

55 If you require a copy of this consultation paper in any other format, e.g. braille, large font, audio, please contact the address below (paragraph 56).

Responding to this consulation

56 The Department would welcome your views on the proposals set out in this document. Please use the response form at Annex A.

Hard copy replies should be sent to:

Miss Karen Savage
Health Protection Branch
Room C4.22
Castle Buildings
Stormont Estate
Belfast
BT4 3SQ

Replies can be sent by fax to 028 9052 8490

Email replies should be sent to : phdadmin@dhsspsni.gov.uk

57 Replies should reach the Department by Wednesday 14th December 2011.

58 A summary of responses will be published in conjunction with any further action.

Responses: confidentiality and disclaimer

59 The Department may publish a summary of responses following completion of the consultation process. Your response and all other responses to the consultation may be disclosed in full on request. The Department can only refuse to disclose information in exceptional circumstances. Before submitting your response please read the paragraphs below.

60 The Freedom of Information Act gives the public a right of access to any information held by a public authority, namely the Department in this case. This right of access to information includes information provided in response to a consultation. The Department cannot automatically consider as confidential information supplied to it in response to a consultation. However, it does have the responsibility to decide whether any information provided by you in response to this consultation including information about your identity should be made public or be treated as confidential.

61 This means that information provided by you in response to the consultation is unlikely to be treated as confidential except in very particular circumstances. The Lord Chancellor's Code of Practice on the Freedom of Information Act provides that:

(a) the Department should only accept information from third parties in confidence if it is necessary to obtain that information in connection with the exercise of any of the Department's functions and it would not otherwise be provided;

(b) the Department should not agree to hold information received from third parties "in confidence" which is not confidential in nature, and

(c) acceptance by the Department of confidentiality provisions must be for good reasons, capable of being justified to the Information Commissioner.

62 For further information about confidentiality of responses please contact the Information Commissioner's Office or visit: www.informationcommissioner.gov.uk.

ANNEX A

RESPONSE FORM

PROPOSED CONSOLIDATION OF THE MISUSE OF DRUGS REGULATIONS (NORTHERN IRELAND) 2002 INCLUDING AMENDMENTS TO SPECIFIC PROVISIONS AND PROPOSALS RELATING TO THE GOVERNMENT'S RESPONSE TO REMAINING SHIPMAN INQUIRY RECOMMENDATIONS.

NAME: _____

CONTACT DETAILS:

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Are you responding: as an individual ☐ on behalf of an organisation ☐

COMMENTS ON THE PROPOSED CHANGES:

Return to: Miss Karen Savage
Health Protection Branch
Room C4.22 Castle Buildings
Stormont Estate Belfast BT4 3SQ