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

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IMPROVING GOVERNANCE OF CONTROLLED DRUGS

A CONSULTATION DOCUMENT

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IMPROVING GOVERNANCE OF CONTROLLED DRUGS

1. Introduction

1.1 This paper sets out proposals for the management of Controlled Drugs in the context of Clinical and Social Care Governance in Northern Ireland as a direct response to the recommendations made in the Fourth and Fifth Reports of the Shipman Inquiry. While the focus of this paper is, necessarily, on controlled drugs, it provides a model template for accountability across the whole of the Clinical and Social Care Governance matters.

1.2 When considering the proposals in this document it should be remembered that the duties and responsibilities, which will be subsequently formalised in the proposed legislation are, in the main, already carried out by individuals and organisations.

1.3 Reference to Boards in this document means the four health and Social Services Boards, under the current structures, or the new Regional Health and Social Care Board, from 1 April 2009.

2. Background

2.1 The Shipman Inquiry's recommendations concerning monitoring and inspection of Controlled Drugs are set out in its Fourth Report and on Clinical and Social Care Governance in its Fifth report. It is recognised that the recommendations within the Fourth Report substantively related to the situation in Great Britain at the time of the Inquiry and that the controlled drug monitoring arrangements operating in Northern Ireland were most favourably commented upon by the Inquiry Chair at that time.

2.2 The Inquiry identified three major weaknesses in the system of monitoring and inspection of Controlled Drugs in Great Britain: -

a) The lack of overall co-ordination – management of Controlled Drugs in primary care was conducted primarily through inspection of community pharmacies by Chemist Inspection Officers (CIOs)[1] from the local police force, with other aspects of professional practice in community pharmacies being assessed by inspectors from the Royal Pharmaceutical Society of Great Britain (RPSGB)[2];

b) CIOs did not have the professional training or experience to detect unusual clinical practice; and

c) Routine inspections of the management of Controlled Drugs in GP practices had been discontinued when the Regional Medical Service (RMS)[3] was abolished in 1991. Health Authority prescribing advisors who had picked up most of the RMS' other functions had other priorities and were not authorised to inspect GP premises or controlled drug registers.

2.3 To take forward the recommendations on Controlled Drugs the Department of Health (England) has introduced the concept of an Accountable Officer. The legislative base for this has been introduced through a number of provisions within the Health Act 2006 and through the Controlled Drugs (Supervision of Management and Use) Regulations 2006[4]. The proposals in this paper are made against this legislative framework and against the background of the conclusions contained within the Northern Ireland Response to the Shipman Inquiry, namely:

(a) The Departmental Inspectorate, based in the Pharmaceutical Branch of the Department of Health Social Services and Public Safety, will consolidate and augment their current inspection and investigative function both within and out-with the HPSS; and

[1] The police carry out the CIO role in Great Britain. In Northern Ireland the Department's Medicines Inspection and Investigation Team carry out this function.
[2] The Department's Medicines Inspection and Investigation Team carry out this function in Northern Ireland.
[3] This organisation is unique to Great Britain and no equivalent structure exists in Northern Ireland.
[4] Comes into force in England on 1 January 2007 and in Scotland on 1 April 2007

(b) Designated Bodies will appoint an Accountable Officer who will have responsibility for compliance with governance arrangements in relation to controlled drugs.

3. Current Arrangements in Northern Ireland

Department's Medicines Inspection and Investigation Team

3.1 In contrast to GB Northern Ireland has a centralised Inspectorate responsible for medicines control including the monitoring of the production, import/export, possession, supply and administration of Controlled Drugs. These functions are carried out by the Department of Health Social Services and Public Safety's Medicines Inspection and Investigation Team. It has a statutory obligation to ensure compliance with legislative requirements in all areas of medicines control as applies within and outwith the HPSS. As well as monitoring and audit activities the Inspectorate is involved in intelligence gathering, investigation and enforcement. In keeping with its integrated nature and overarching responsibilities, the Medicines Inspection and Investigation Team liaises closely with other statutory bodies, professional bodies, other enforcement agencies locally, nationally and internationally, and commercial groups and representative bodies.

3.2 The Shipman Inquiry identified the key strengths of the current Department's Medicines Inspection and Investigation Team as *inter alia*, its: -

a) centralised nature, facilitating the gathering and collation of intelligence to inform the inspection process;

b) integration within the Department;

c) expertise and multi-disciplinary nature; and

d) existing integration and collaboration with other professional bodies and investigation/enforcement authorities.

3.3 Alongside the acknowledged strengths of the current processes, the Department is committed to augmenting the arrangements and to add further rigour to the governance processes which will ensure appropriate standards of handling of Controlled Drugs, detect and deter poor practice and deliberate wrongdoing, and protect the safety of patients. This would contribute to: -

- ensuring that all healthcare professionals who work with Controlled Drugs in any way are subject to equivalent standards of monitoring and inspection irrespective of the setting in which they work; and

- the development of partnerships between healthcare professionals and those professionals with an inspection or law enforcement background and in so doing, maximising the possibility for deterring or detecting malpractice.

4. Health Act 2006

4.1 The Health Act 2006 contains three provisions in relation to the Fourth Report of the Shipman Inquiry: -

- the appointment of an Accountable Officer by Designated Bodies, with the duties of the Accountable Officer encompassing the development and monitoring of systems to ensure the safe and effective use and management of Controlled Drugs within the organisation subject to their oversight;

- a duty to collaborate and share intelligence on Controlled Drugs by Responsible Bodies. Responsible Bodies will include, among others, those organisations who are directly or indirectly concerned with the provision of health and social care, supply or administer controlled drugs or have powers of inspection in relation to the management of Controlled Drugs. The Duty of

Collaboration will place a legal duty on Responsible Bodies to share (within certain constraints) information and intelligence regarding the use of Controlled Drugs in the health and social care sector; and

- a power of entry and inspection for certain Authorised Persons.

4.2 It is envisaged that these provisions will allow the management and use of Controlled Drugs within healthcare organisations to be more effectively monitored and audited, without impacting on patient care. The Act provides enabling powers for Northern Ireland to take forward its own subordinate legislation in order to introduce suitable arrangements for the management of Controlled Drugs.

5. Proposals for Northern Ireland

5.1 In developing proposals on the way forward in Northern Ireland the following areas were considered, and where appropriate evaluated options that would take account of our specific needs were developed and evaluated: -

a) Designated Bodies;

b) Role of the Accountable Officer;

c) Routine Inspection;

d) Duty of Collaboration; and

e) Investigating Concerns.

The implementation of these proposals will have possible resource implications for some Health and Social Care (HCS) organisations, other identified bodies outside HSC and the Department. It is difficult to provide accurate details on funding required for the roll out of these proposals at this stage as it is not possible to make comparisons to the

models adopted in England due to the different structures that exist in the management of health and social care services.

Designated Bodies

5.2 Under the arrangements for Northern Ireland it is proposed HSC organisations, and other identified bodies outside the HSC, would become Designated Bodies, similar to England. Each of these Bodies would be required to appoint Accountable Officers for the purposes specified in order to effect a strengthening of the internal audit assurance control. It is proposed such bodies would include, under the current HSC structures, for example, the Boards, 5 Health and Social Care Trusts, NI Ambulance Service Trust and Independent Hospitals.

5.3 Individual General Medical practices Family Practitioner Services are provided by General Medical Practitioners, Pharmacists, Optometrists and Dentists, Each of these are independent contractors, who contract with their Board to provide a range of primary care services. Because of their status as independent contractors they would not be viewed as Designated Bodies under the arrangements. In order to preserve independence and objectivity it is proposed that the Boards, as the commissioning organisations, would be the Designated Bodies. This responsibility would then transfer to the new Regional Health and Social Care Board from 2009. This proposal is consistent with the structures and arrangements being taken forward in England under the legislation and we consider no reason to deviate from this.

Role of the Accountable Officer in Northern Ireland

5.4 The Fourth Shipman Report, the Health Act 2006 and the Controlled Drugs (Supervision of Management and Use) Regulations 2006 make clear the role of Accountable Officers on Controlled Drugs matters in England. Account has been taken of this in developing the role of the Accountable Officer in Northern Ireland.

5.5 Irrespective of any regulatory changes, all individuals and bodies have a responsibility to comply with the law. Indeed, this is fundamental to governance procedures within HSC organisations. Thus, the appointment of an Accountable Officer will **not** change personal or corporate responsibility but will ensure that such systems and management arrangements are in place to enable a Designated Body to be fully compliant.

5.6 In Northern Ireland it is proposed that the Chief Executive of the Designated Body would be appointed as the Accountable Officer under the new legislation to be introduced in Northern Ireland. This would be concurrent with the broader accountability responsibilities of the Chief Executive for all matters pertaining to his/her organisation. It places responsibility therefore at the highest level within the organisation.

5.7 Whilst the Accountable Officer will be the Chief Executive of the Designated Body and will carry overall responsibility for ensuring compliance with monitoring and inspection arrangements for Controlled Drugs and other Clinical Governance issues, it is anticipated that the day-to-day discharge of these responsibilities will be undertaken by Designated Officers. These Officers will be responsible for providing appropriate assurances to the Accountable Officer, who will exercise overall governance responsibility. In this context the Accountable Officer would be seen as both independent and objective. Moreover, it will help ensure the system is not open to criticisms of self-regulation.

5.8 By way of example, in Secondary and Community Care the Accountable Officer within a Health and Social Care Trust exercising his/her responsibilities for the management of Controlled Drugs will appoint a Designated Officer(s) with detailed experience of these issues. It is suggested that the Chief Pharmaceutical Officer within the Trust would be the appropriate person for appointment as the Controlled Drug Designated Officer. However, he/she would be required to work with colleagues within the hospital setting and across other areas of the Trust's activities to monitor and evaluate the use and

management of controlled drugs, in order to provide the required assurances to the Chief Executive.

5.9 In the Primary Care setting the relationship will be somewhat different as a Commissioning organisation (the Designated Body) will be required to gain assurances over each of the independent contractors and for the system as a whole. In this case the Accountable Officer would be the Chief Executive within the Boards. In turn they would be responsible for taking whatever action was necessary to gain assurances over the governance and management of controlled drugs for each of the Family Practitioner Service groupings or with any other organisation or body the Commissioning organisation has a contract with for the delivery of primary care services, e.g. Out of Hours contractors.

5.10 As is the case in the rest of the UK, it would be anticipated that the additional duties falling to Chief Executive Officers or other designated staff would be absorbed by redeployment of existing resources within the Designated Body with minimal additional costs.

5.11 The Department however will be required to develop administrative and IT systems so as to carry out such functions as maintaining a register of Accountable Officers and provide for their training. For the most part It is envisaged that this will be met through redeployment of resources however some additional funding will be required to meet IT and training costs.

Routine Monitoring

5.12 It is crucial to appreciate the existing independent, albeit distinctive, inspectorate roles of the Department's Medicines Inspection and Investigation Team and that of the Regulation and Quality Improvement Authority (RQIA). The Department fully recognises the role of the RQIA in pursuit of its function across the HPSS, independent and voluntary sectors. In broad terms the Department's Medicines Inspection and Investigation Team is primarily responsible

for ensuring compliance with medicine related legislation and taking action where non-compliance has been judged to have occurred. RQIA on the other hand, focus on service performance in respect of care services provided to patients and clients. Taking account of this, two options have been considered.

5.13 Recognising that there are clear differences of function, there are also dual interests in respect of quality and safety. Helpfully, the legislation underpinning RQIA makes provision for collaborative action in areas where there is duality of interest or responsibility, and the development of a memorandum of understanding between the two groups is ongoing to ensure appropriate effective and efficient inspection processes to be carried out without causing unnecessary duplication of roles and responsibilities

5.14 It is proposed to develop, strengthen, enhance and adapt the current inspection programmes by both the Department's Medicines Inspection and Investigation Team and RQIA so that they can continue to deliver their existing primary and secondary care inspections and to offer an independent assurance process to Accountable Officers through an agreed inspection and monitoring programme.

5.15 This proposal closely mirrors the findings of the Shipman Inquiry Report, which recognised the unique strengths of the Northern Ireland system. Formal inspection of healthcare and social care providers involving an 'on-site' visit to the provider's premises remains a critical element of the new monitoring and inspection arrangements providing a useful tool to check physical arrangements for the storage, record keeping and management of Controlled Drugs, to support individuals (particularly Accountable Officers and Designated Officers), promote organisational development, and to identify and investigate concerns. Monitoring may also involve remote auditing of systems for the management of drugs through use of declarations and self-assessments. The inspection arrangements in Northern Ireland have been subject to intense independent evaluation and have been endorsed as the most comprehensive system operating anywhere

within the United Kingdom. Any deconstruction of the current inspection arrangements would be detrimental to patient safety and contrary to comments in the Shipman Reports and to Ministerial response.

5.16 The new arrangements will provide a power of entry and inspection for the Accountable Officer and any Designated Officers appointed to facilitate the inspection of Controlled Drugs.

5.17 In secondary care, it would be envisaged that as in other parts of the UK, this would be achieved in the main through existing resources, particularly as it is proposed the Department would offer an independent external audit function. Organisations would however need to consider implications for any additional administration support on their part.

5.18 In the primary care setting routine monitoring would be delivered by a moderate progression of the current practice visits undertaken by Boards' dental/medical/prescribing advisors to include greater scrutiny of controlled drugs issues with adverse issues being investigated as above. This is currently being developed by Board Prescribing Advisors and the Department's Medicines Inspection and Investigation Team. Boards will need to take a view whether these costs and any additional administration costs can be absorbed or whether some further funding is required.

5.19 Similarly, for independent healthcare providers, and nursing and residential homes, it is anticipated that the RQIA will manage this workload as part of their existing inspection processes.

5.20 Considering the need to ensure appropriate scrutiny across the spectrum of Responsible Bodies extends, *inter alia*, to community pharmacies, general medical and dental practitioners, private clinics, nursing and care homes, out-of-hours facilities, controlled drug licence holders and Trust hospitals, it is likely the Department will require additional inspection and administrative resources. In determining the

resourcing needs account should be taken of the robust systems and structures inherent in a well established and fully deployed Medicines Inspection and Investigation Team.

Duty of Collaboration

5.21 In line with other jurisdictions, a legal duty of collaboration will be included in the proposed legislation which will introduce the Accountable Officer role in Northern Ireland. This will place a legal duty on Responsible Bodies to share information and intelligence, (within certain constraints), about the use of Controlled Drugs in the health care sector. Those bodies required to share information will include the Department's Medicines Inspection and Investigation Team, RQIA, healthcare organisations, Police Service for Northern Ireland, Social Service authorities, other relevant inspectorates and professional bodies.

5.22 It will be critical to ensure that systems and processes are in place to facilitate timely and appropriate sharing of information. In keeping with developments in England, this would best be facilitated by the establishment of a Local Intelligence Network (LIN). The network would enable Agencies that have a cause for concern about the activities of any healthcare professional or organisation, to share them as soon as possible with any other local Agencies who may be affected or who may have complementary information. While joint action may be agreed, each Agency would retain responsibility for taking appropriate action where required.

5.23 It is proposed to establish a single Local Intelligence Network. This multidisciplinary /multi-agency group would represent all stakeholders on a Northern Ireland-wide basis and would meet routinely or in response to issues of concern in order to share intelligence and to agree responses.

5.24 In arriving at this proposal account was taken of the size of the NI population in comparison to other parts of the UK and it was concluded

that fragmenting the intelligence sharing pool in Northern Ireland would result in lost intelligence and possible unnecessary duplication of effort.

5.25 It is envisaged that the Department's Medicines Inspection and Investigation Team would offer a critical resource to the LIN particularly as the Inspectorate is central to already matured intelligence networks (local, national and international) currently in existence here. Additionally, it would be crucial that this forum takes account of the diversity of interests both within and outwith the health service including manufacturers, wholesalers and Veterinary Practitioners.

5.26 It is unlikely this proposal will have additional costs for designated or responsible bodies as it relates solely sharing of information.

5.27 The Department will however require funding to host the LIN as it will be required to develop and maintain an IT system, compatible with the GB database currently being considered in order to allow Responsible Bodies to share information. The Department will also be required to provide LIN training for representatives of Designated and Responsible Bodies.

Investigating Concerns

5.28 Accountable Officers will be required to develop and implement systems for routinely monitoring the use of Controlled Drugs and Clinical Governance issues through pro-active analysis and through the identification of triggers which identify areas of concern, to log these concerns, and to initiate appropriate investigations.

5.29 Concerns may come to light through a variety of routes – including routine monitoring of prescribing data, routine inspections, and patient complaints or from reports by health or social care professionals. Where concerns are serious - for example, if there are serious professional's fitness to practise issues and where patient safety is at risk, the concerns should be passed on to the relevant body

immediately. However, it is recognised there may be cases where further investigation is warranted.

5.30 To address this it is proposed that the Medicines Inspection and Investigation Team within the Department becomes a Centre of Investigative Excellence, which would be available to all Accountable Officers on a regional basis.

5.31 It is seen that a Centre of Investigative Excellence as this would reduce unnecessary duplication of effort, increase the intelligence pool, ensure independence and consistency, and ultimately assist Accountable Officers in ensuring there is a clear separation between investigation and decision-making.

5.31 It is anticipated this proposal would have minimal additional costs for designated and responsible bodies as preliminary internal investigations would be carried out as at present.

5.32 Currently, the Department's Medicines Inspection and Investigation Team carry out investigative work across a range of health care arenas including community pharmacies, general medical and dental practices, private clinics and controlled drug licence holders. Accepting that increased scrutiny will lead to increased investigative action and considering the need to augment the range of investigative activities across the full spectrum of Responsible Bodies to include, *inter alia*, nursing and care homes, out-of-hours facilities and Trust hospitals, it is recognised that additional investigative and administration support would be required. The extent of any additional resources will take account of the robust systems and structures within the Department's Medicines Inspection and Investigation Team

6. Next Steps

Agree Designated and Responsible Bodies

6.1 The Health and Social Care structures in Northern Ireland are unique and therefore do not correspond with those operating elsewhere in the

United Kingdom. The Department will therefore agree in consultation with relevant HCS organisations which organisations will be classified as Designated and Responsible Bodies in Northern Ireland for the purposes of the proposed legislation and the appointment of Accountable Officers.

Legislation

6.2 The Department proposes to bring forward subordinate legislation to enable

- appointment of an Accountable Officer by Designated Bodies;
- collaboration and sharing of intelligence on Controlled Drugs; and
- power of entry and inspection for certain Authorised Persons, which will facilitate the inspection of Controlled Drugs.

Identify and Appoint Accountable Officers and Develop Training Programme and Guidance

6.3 Under the proposed legislation Designated Bodies will be required to appoint Accountable Officers and to ensure the responsibilities are exercised. A Training Programme and Guidance will be developed and made available to Designated Bodies and Accountable Officers.

Standards and Training

6.4 To implement these new arrangements, common standards will be developed for developmental and inspection visits, as will a competency framework for those involved in developmental, inspection and/or enforcement visits.

6.5 Based on a competency framework, the Department will work with professional and educational organisations to ensure access to suitable initial and update training for those involved in developmental,

inspection and/or enforcement work. Where possible, such training will be multiprofessional.

Collaborative Action

The following actions are proposed: -

- the Department in conjunction with other Responsible Bodies will develop and agree roles to support collaborative action;

- develop and agree a Memorandum of Understanding between the Department's Medicines Inspection and Investigation Team and RQIA;

- establish a local intelligence network within and outwith the HPSS to enable the sharing of information across all bodies; and

- where Designated Bodies wish to use the Department's Medicines Inspection and Investigation Team this should be set out in agreed Service Level Agreements.

7. Equality Impact Assessment

7.1 In line with the commitments in its Equality Scheme, the Department has conducted a Preliminary Equality Impact Assessment (PEQIA) on the policy changes. The PEQIA did not identify any potential for adverse impact on any of the nine equality categories.

8. Conclusion

8.1 In Northern Ireland a **three-pronged** approach will be applied to the governance arrangements concerning Controlled Drugs:

- Designated Bodies will appoint an Accountable Officer who will have responsibility for compliance with governance arrangements in relation to Controlled Drugs;

- a single Local Intelligence Network will be established to collate, share and respond to gathered intelligence; and

- the Department's Medicines Inspection and Investigation Team, working collaboratively with other key stakeholders (particularly RQIA), will consolidate and augment current inspection and investigative functions in line with Ministerial Intentions both within and outwith the health service to provide assurance that internal controls are appropriate, to facilitate the collation and distribution of intelligence and to offer a centralised investigation facility.

8.2 This three-strand approach will provide an assurance that the robust systems already in place in Northern Ireland (as acknowledged within the Shipman Inquiry Reports) will be augmented to continue to provide, arguably, the most comprehensive controlled drug monitoring system in the United Kingdom. As has previously been indicated, it is the Department's intention to build upon the positive endorsement provided by the Shipman Inquiry of the current inspection arrangements in Northern Ireland. The model proposed seeks to emulate this objective, allowing of course, that some refinement may be necessary in individual contexts and within resource constraints.

8.3 This consultation document seeks your views on the proposed policy changes which will be taken forward in subordinate legislation. In particular we invite your comments on the following questions: -

(A) Has the right balance been achieved in strengthening controls and ensuring safer management and use of controlled drugs?

(B) Do the proposed arrangements make best use of the existing mechanisms?

(C) Any additional comments on the proposals?

Your views are important to us and will help us shape the proposed regulations. We invite responses to this consultation by 11 October 2008.

Responses should be sent by post, fax or email to:

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8.4 If you require further copies of this document or require it in another format please contact Chris Scantlebury at the address set out in paragraph 8.3. This document is also available on the Department's website at the following address
www.dhsspsni.gov.uk/index/consultations

Appendix 1

Freedom of Information Act 2000 – Confidentiality of Consultations

1. 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 on request. The Department can only refuse to disclose information in exceptional circumstances. Before you submit your response, please read the paragraphs below on the confidentiality of consultations and they will give you guidance on the legal position about any information given by you in response to this consultation.

2. 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.

3. 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:

- 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
- the Department should not agree to hold information received from third parties "in confidence" which is not confidential in nature
- acceptance by the Department of confidentiality provisions must be for good reasons, capable of being justified to the Information Commissioner

For further information about confidentiality of responses please contact the Information Commissioner's Office (or see web site at: http://www.informationcommissioner.gov.uk/)

Appendix 2

CONSULTATION LIST

All Northern Ireland Party Leaders
Other Northern Ireland Parties
MPS and MEPs who are not Party Leaders or MLAs
Committee for Health, Social Services and Public Safety Members
OFMDFM, Machinery of Government Division
OFMDFM, Central Management Unit
Northern Ireland Office – Devolution and Legislation Division
Legal Deposit Libraries
Departmental Library
Chief Executives – Health and Social Services Boards
Directors of Primary Care - Health and Social Services Boards
Directors of Public Health – Health and Social Services Boards
Chief Executives of Health Social Care Trusts
Chief Executive - Central Services Agency
Chief Executives of Health and Social Services Councils
Royal College of General Practitioners (NI)
General Practitioners Committee (NI)
National Clinical Assessment Authority (NI)
Ambulance Service of Northern Ireland
Blood Transfusion Service
NI Medical and Dental Training Agency
NI Centre for Postgraduate Pharmaceutical Education and Training
NI Practice and Education Council for Nursing and Midwifery
General Medical Council (NI)
British Medical Association
British Dental Association
Royal College of Nursing
Ulster Chemists Association
Pharmaceutical Contractors Committee
Pharmaceutical Society of Northern Ireland
Health Professions Council
Optometry Northern Ireland
Ministry of Defence
Prison Service for Northern Ireland
Police Service of Northern Ireland
Independent Clinics in Northern Ireland