# EXPLANATORY MEMORANDUM TO

# THE CONTROLLED DRUGS (SUPERVISION OF MANAGEMENT AND USE) REGULATIONS (NORTHERN IRELAND) 2009

## 2009 No. 225

## 1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health, Social Services and Public Safety to accompany SR No. which is laid before the Northern Ireland Assembly.

1.2 The statutory rule is made under powers in Chapter 1 of Part 3 of the Health Act 2006 and is subject to negative resolution procedure.

1.3 The rule is due to come into operation on 1st October 2009.

## 2. Purpose

2.1 The purpose of this statutory rule is to enhance governance arrangements for controlled drugs. The Regulations set out the requirements for Designated Bodies to appoint an Accountable Officer and describe the duties and responsibilities of Accountable Officers to improve the management and use of controlled drugs. The Regulations also require specified bodies to co-operate with each other, with regard to the sharing of information about concerns in relation to the use and management of controlled drugs, and set out arrangements relating to powers of entry and inspection. These provisions form a key part of the Northern Ireland response to the fourth report from the Shipman Inquiry, which focussed on controlled drugs.

## 3. Background

3.1 The Shipman Inquiry exposed a number of loopholes in the management of controlled drugs. Regulation is necessary to respond to the findings of the Inquiry to ensure that the management of controlled drugs is tightened up to reduce the risk of harm to patients and the risk of illegal diversion.

3.2 Current legislation including The Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations (Northern Ireland) 2002 subject certain drugs “controlled drugs” to special legislative control because of their potential to be abused and cause harm. Individuals retain responsibility for following this legislation, but under these Regulations, Accountable Officers will have an overarching responsibility to ensure that their organisation or those working on its behalf have arrangements in place to comply with misuse of drugs legislation.

3.3 These Regulations make use of the powers in Chapter 1 of Part 3 of the Health Act 2006 which extend to Northern Ireland and makes provision for:-

- the appointment of an Accountable Officer by Designated Bodies.

- a duty for Responsible Bodies to share information and intelligence regarding the use and management of controlled drugs.

- a power of entry and inspection for certain authorised persons in relation to records and stocks of controlled drugs.

3.4 The Regulations specify that Designated Bodies will be required to appoint an Accountable Officer to ensure that the organisation has proper arrangements in place for the safe management and use of such drugs. In primary care services the Accountable Officer of the Health and Social Care Board will ensure that its contractors, such as GP and dental practices, have appropriate arrangements in place.

3.5 Accountable Officers are required to be of sufficient seniority and suitably removed from the day-to-day management of controlled drugs. Under the Regulations, they are given certain duties and responsibilities to ensure the safe management and use of controlled drugs. These include monitoring and auditing the management and use of controlled drugs within their Designated Body and also monitoring and auditing any persons or bodies acting on behalf of, or providing services under arrangements made with the Designated Body. This may include carrying out periodic inspections and investigating concerns about the use of controlled drugs, and undertaking appropriate action.

3.6 The Regulations also set out the bodies which are required to share information about controlled drugs and to co-operate generally with regard to cases where intervention may be necessary. The information sharing requirements are intended to ensure concerns about the management and use of controlled drugs by health and social care professionals can be appropriately shared and action co-ordinated, in order to protect the public from harm.

3.7 In order to ensure that Accountable Officers can fulfil their responsibilities to ensure the safe management of controlled drugs, for example where they have concerns about storage, they have powers of entry and inspection in relation to the premises used in the connection with the management or use of controlled drugs. Routine inspections and assessments of controlled drugs will however only be needed for bodies that are not already subject to periodic inspections by the Health and Social Care Regulation and Quality Improvement Authority or the Department.

## 4. Matters of special interest to the Committee for Health, Social Services and Public Safety

4.1 These Regulations make provisions to further strengthen the current governance arrangements for controlled drugs. They replicate measures, as far as possible, which came into force in England and Scotland in 2007 and in

Wales in 2009. The Committee noted the consultation document which included the draft Regulations at its meeting on 30 April 2009.

## 5. Consultation

5.1 The principles of the new governance arrangements set out in the Regulations were subject to a three month consultation which commenced on 1 August 2008. In general the thirteen respondees to the consultation considered that the right balance had been achieved in strengthening controls and ensuring safer management and use of controlled drugs. They also considered that the proposals made best use of existing mechanisms.

5.2 A further 6 week consultation on the draft Regulations commenced on 6 April 2009. In general comments received from the six respondees related to the implementation of the regulations and the need for appropriate training. The Department has taken steps to ensure that those who will have responsibility under the above regulations are trained in advance of the legislation coming into operation on 1 October 2009.

## 6. Equality Impact

6.1 Consideration was given to equality and human rights implications of the provisions introduced by these Regulations at policy development stage. They were considered compatible with Sections 24 and 75 of the Northern Ireland Act 1998. No potential for adverse impact on any of the nine equality categories was identified.

## 7. Regulatory Impact

7.1 The provisions introduced by these regulations include the appointment of an Accountable Officer by Designated Bodies, a duty to collaborate and share intelligence on controlled drugs by certain organisations and a power of entry and inspection for certain authorised persons. These requirements will only apply to public sector organisations and independent hospitals. Although some independent hospitals may fall within the definition of "small business" or "charities" it was considered that the requirement to appoint an Accountable Officer and comply with the legislative requirements will impose negligible costs to the organisations, therefore a full Regulatory Impact Assessment was not prepared in respect of the provisions being taken forward in these Regulations. The attendance at the Local Intelligence Network and the support provided to the Accountable Officers through training sessions and supporting information is considered beneficial to the smooth running of the organisations.

## 8. Financial Implications

8.1 The implementation of the provisions included in these regulations will have resource implications for the Health and Social Care Board (HSCB) and the Department. With regard to the HSCB it is anticipated that the additional demands associated with the devolved monitoring responsibility will be taken

into account when appointing the Pharmacy and Medicines Management team. Equally the Department is seeking to secure appropriate resources to fulfil its responsibilities which include assisting Designated Bodies develop operational activities, developing and maintaining the single Local Intelligence Network, maintaining a register of Accountable Officers, and training and development activities. The Regulations consolidate the auditing and monitoring of controlled drugs, the investigation of concerns and the sharing of information that are currently undertaken by the Trusts and the Independent Hospitals regarding controlled drugs. The financial implications of the new provisions such as attendance at the Local Intelligence Network and the completion of self-assessments and declarations are considered minimal.

## 9. Contact

9.1 For further information on these regulations please contact:

Shona Coy
Principal Pharmaceutical Officer
Pharmaceutical Advice and Services
Castle Buildings
Stormont
Belfast
BT4 3SQ
Tel (028) 9052 2669