



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

National Policy for Nurse and Midwife Medicinal Product Prescribing



Changing practice to support service delivery



Tús Áite do
Shábháilteacht **1** Othar
Patient Safety **1** First



Office of the
Nursing & Midwifery
Services Director



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

National Policy for Nurse and Midwife Medicinal Product Prescribing

Document reference number:	HSE/NMP/01/01 V1	Document drafted by:	Office of the Nursing and Midwifery Services Director, Health Service Executive
Supersedes:	Previous NP policies x 3: PCCC/NP/01/01 V1, 04/09/09 NHO/NP/01/01 V1, 23/09/09 NFVB/NMPP/01/01 V2, 17/12/10	Document approved by:	Name: Dr Michael Shannon Nursing and Midwifery Services Director, Office of the Nursing and Midwifery Services Director Signature:  Name: Dr Barry White Clinical Strategy and Programmes National Director Signature:  Name: Ms. Laverne Mc Guinness National Integrated Services Director Signature:  Name: Dr Philip Crowley Quality and Patient Safety Directorate Signature: 
Approval date:	01/03/2012	Responsibility for implementation:	Directors of Services
Revision date:	01/03/2014	Responsibility for evaluation and audit:	Directors of Services
		Number of Pages:	67

Table of Contents

1.0	Policy Introduction	4
1.1	Legislation, Regulation and Rules	4
1.2	Professional Regulation	5
1.3	Implementation Framework	5
1.4	Hospital, Community and Public Health Integrated Services	6
2.0	Policy Statement	7
3.0	Purpose	8
4.0	Scope	8
5.0	Glossary of Reference	9
6.0	Roles and Responsibilities	14
6.1	Regional Director of Operations/Area Manager	14
6.2	The Director of Nursing and Midwifery	14
6.3	Line Manager of Candidate or Registered Nurse Prescriber	16
6.4	Prescribing Site Coordinator	17
6.5	Potential Applicants	17
6.6	Candidate Nurse Prescriber	18
6.7	Registered Nurse Prescriber	18
6.8	The Medical Mentor	20
6.9	The Drugs and Therapeutics Committee	20
6.10	The Collaborating Medical Practitioner(s)	21
6.11	The Pharmacist	22
7.0	Eligibility to Prescribe	23
7.1	Conditions	23
7.2	Validation of Collaborative Practice Agreement and Registration with An Bord Altranais	23
7.3	Termination of the Collaborative Practice Agreement	24
8.0	Clinical Indemnity	26
8.1	The State Claims Agency Clinical Indemnity Scheme	26
9.0	Community Drug Prescribing Schemes	26
9.1	Primary Care Prescription Form	26
10.0	Procedure	28
10.1	Clinical Decision-Making Process	28
10.2	Communication, History Taking and Documentation	28
10.3	Guidance for Prescription Writing in Practice	29
10.4	Prescription Writing for Schedule 8 – Controlled Drugs	30
10.5	Separation of Responsibilities in the Medication Management Cycle	31
10.6	Repeat Prescribing	31
10.7	Prescribing of Unauthorised Medicinal Products and Authorised Medicinal Products Prescribed for an Unauthorised Indication (Off-Label)	32

10.8	Security and Safe Handling of Prescription Pads	33
10.9	Adverse Drug Reactions	33
10.10	Medication Errors / Near Misses	34
11.0	Monitoring and Audit	35
11.1	Verification of Prescribing Status	35
11.2	Monitoring Nurse and Midwife Medicinal Product Prescribing	35
11.3	Audit of Nurse and Midwife Medicinal Product Prescribing	35
	Reference List	37
	Bibliography	40
	Appendix A: Policy Reviewers Acknowledgement	
	Appendix B: Principles for Clinical Governance Development	
	Appendix C: Schedule 8 Drugs	
	Appendix D: Statement from State Claims Agency on Nurse and Midwife Medicinal Product Prescribing	
	Appendix E: State Claims Agency Statement on Unauthorised (Exempt) and Authorised Medicines Prescribed for an Unauthorised Indication (Off-Label)	
	Appendix F: Alignment of Community Drug Schemes to incorporate nurse and midwife prescriptions (Circular No. SO222/NCO/09 / Circular No. 013/2011)	
	Appendix G: HSE RNP Guidance Process Regarding the Prescribing of Medications for “Off-Label” use	

Signature Sheet:

I have read, understand and agree to adhere to the attached policy

Print Name	Signature	Area of Work	Date

1.0 Policy Introduction

The prescribing of Medicinal Products is an expanded role and as such one that nurses and midwives agree to undertake, having regard to professional regulation, guidelines, legislation and both national and local organisational policies. Prescriptive authority for nurses and midwives is founded on a dual framework of medicines legislation and professional regulation. This policy has therefore been developed in partnership with key stakeholders to comply with the Health Service Executive (HSE) statutory obligations and to give practical effect to the governing legislation, regulation, rules and An Bord Altranais guidance documents.

Health service providers introducing nurse and midwife medicinal product prescribing should be cognisant of the Principles for Clinical Governance Development of the HSE (Appendix B). This framework supports health care teams who are accountable for the quality and safety in the care they deliver to their patient/client/service users.

1.1 Legislation, Regulation and Rules

Following public consultation undertaken by the Department of Health and Children the following was signed into law on 1 May 2007:

- *Irish Medicines Board (Miscellaneous Provision) Act 2006* (No. 3 of 2006) (Section 10 (1(ii)))
- *Irish Medicines Board (Miscellaneous provisions) Act 2006* (Commencement) Order 2007
- *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007*, Statutory Instrument No. 201 of 2007
- *Misuse of Drugs (Amendment) Regulations 2007*, Statutory Instrument No. 200 of 2007
- *Nurses Rules* (An Bord Altranais, 2007)

To give effect to nurse and midwife medicinal product prescribing for the Drugs Payment Scheme (DPS) the following was signed into law on 25 February 2009:

- *Irish Medicines Board (Miscellaneous Provisions) Act 2006* (Commencement) Order Statutory Instrument No 67 of 2009

The Regulations associated with the *Irish Medicines Board (Miscellaneous Provisions) Act, 2006* attach the following conditions which must be met where nurse or midwife medicinal product prescribing takes place:

- *the nurse or midwife must be employed by a health service provider in a hospital, nursing home, clinic or other health service setting (including any case where the health service is provided in a private home)*
- *The medicinal product is one that would be given in the usual course of service provided in the health service setting in which the nurse or midwife is employed*
- *the prescription is in fact issued in the usual course of the provision of that health service*
- *An Bord Altranais registration number (also known as the Personal Identification Number (PIN)) must be stated on the prescription*

The regulations do not inhibit the right of an employer to impose further restrictions including prohibiting a nurse or midwife from prescribing. The prescribing of controlled drugs is detailed in the *Misuse of Drugs (Amendment) Regulation 2007* (MDA), which stipulates conditions for establishing a separate Schedule 8 and restriction for prescribing Schedule 2 and 3 medicinal products. Only registered nurse prescribers working in stipulated health care settings have the authority to prescribe named Schedule 8 drugs (Appendix C).

1.2 Professional Regulation

This policy adheres to the regulatory framework and has been developed in conjunction with the guidance issued by An Bord Altranais including:

- *Collaborative Practice Agreement for Nurses and Midwives with Prescriptive Authority 3rd edn* (An Bord Altranais, 2012).
- *Guidance to Nurses and Midwives on Medication Management* (An Bord Altranais, 2007)
- *Practice Standards for Midwives*, (An Bord Altranais, 2010)
- *Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority, 2nd edn* (An Bord Altranais, 2010)
- *Requirements and Standards for Education Programmes for Nurses and Midwives with Prescriptive Authority* (An Bord Altranais, 2007)
- *Recording Clinical Practice. Guidance to Nurses and Midwives* (An Bord Altranais, 2002)
- *Review of the Scope of Nursing and Midwifery Practice: Final Report* (An Bord Altranais, 2000)
- *The Code of Professional Conduct for Each Nurse and Midwife* (An Bord Altranais, 2000)

1.3 Implementation Framework

The Office of the Nursing and Midwifery Services Director, Health Service Executive, is responsible for leading the national implementation of nurse and midwife medicinal product prescribing in Ireland. To this end, the Office has published the following guidance documents:

- *Guiding Framework for the Implementation of Nurse and Midwife Prescribing in Ireland* (Office of the Nursing Services Director, 2008)
- *Nurse and Midwife Medicinal Product Prescribing Application Guidelines for the Education Programme: Information for Health Service Providers, Nurses and Midwives and Mentors, 2nd edn* (Office of the Nursing and Midwifery Services Director 2011)
- *Medicinal Product Authorisation Information and Frequently Asked Questions for Registered Nurse Prescribers* (Office of the Nursing and Midwifery Services Director, 2011)
- *Information and Guidance on the Introduction of Nurse and Midwife Medicinal Product Prescribing in General Practice* (Office of the Nursing and Midwifery Services Director, 2011)
- *Patient Information Leaflets, Adult and Children* (Office of the Nursing Services Director, 2008: available at <http://www.hse.ie/go/nurseprescribing>)
- *DVD titled Nurse and Midwife Prescribing: A Prescription for Practice* (Office of the Nursing and Midwifery Services Director, 2011)

1.4 Hospital, Community and Public Health Integrated Services

Designing and delivering services, to ensure high quality safe services for all our patients and clients, is our primary concern. We are focusing on the development and implementation of safe quality healthcare, where all service users attending our services receive high quality treatment at all times, are treated as individuals with respect and dignity, are involved in their own care, have their individual needs taken into account, are kept fully informed, have their concerns addressed and are treated/cared for in a safe environment based on best international practice. (Health Service Executive, National Service Plan, 2012: p18).

Health service providers introducing nurse or midwife medicinal product prescribing should familiarise themselves with the relevant regulatory, strategy, policy and standards documents identified and listed throughout this policy, as well as those listed below:

- *An Integrated Health System for Ireland (Health Service Executive, 2008)*
- *Building a Culture of Patient Safety: Report of the Commission on Patient Safety and Quality Assurance (Government of Ireland, 2008)*
- *Children First: National Guidelines for the Protection and Welfare of Children (Department of Health and Children, 2009)*
- *Guidance on Developing Key Performance Indicators and Minimum Data Sets to Monitor Healthcare Quality (Health Information and Quality Authority, 2010)*
- *Guidance on Privacy Impact Assessment in Health and Social Care. (Health Information and Quality Authority, 2010)*
- *Mental Health Act, Number 25 of 2001 (Government of Ireland, 2001)*
- *National Disability Strategy (Department of Health & Children, 2005)*
- *National Quality Standards for Residential Care Settings for Older People in Ireland (Health Information and Quality Authority, 2008)*
- *National Quality Standards: Residential Services for People with Disabilities (Health Information and Quality Authority, 2009)*
- *National Service Plan (Health Service Executive, 2012)*
- *Primary Care: A New Direction (Department of Health and Children, 2001)*
- *Professional Guidance for Nurses working with Older People (An Bord Altranais, 2009)*
- *Quality and Fairness: A Health System for You (Department of Health and Children, 2001)*
- *Report and Recommendations on Patient Referrals from General Practice to Out Patients and Radiology Services including the National Standard for Patient Referral Information (Health Information and Quality Authority, 2011)*
- *Strategic Framework for Role Expansion of Nurse and Midwife: Promoting Quality Patient Care (Department of Health and Children, 2011)*
- *Transformation Programme 2007- 2010 (Health Service Executive, 2006)*
- *Vision for Change: Report of the Expert Group on Mental Health (Department of Health and Children, 2006)*

2.0 Policy Statement

The prescribing of medicinal products is an expanded role and, as such, one that nurses and midwives agree to undertake, having regard to professional regulation, guidelines, legislation and both national and local organisational policies.

Each nurse and midwife is individually accountable to keep up-to-date with advances in prescribing and clinical practice and must acknowledge any limitations in competence. Practising in an accountable manner requires a sound knowledge-base upon which to make decisions in conjunction with professional judgement. The registered nurse prescriber must be able to justify and provide a rationale for taking a particular course of action.

Individual healthcare providers can develop addenda in relation to local policy requirements. They may also identify specific requirements and responsibilities for nurse and midwife prescribers to meet their patient/client/service users and service needs.

3.0 Purpose

This national policy has been developed to support a standardised approach to the implementation of nurse and midwife medicinal product prescribing in the voluntary and statutory services of the HSE. This policy is underpinned by a clear set of principles and criteria within the overall clinical governance framework, legislation, professional regulation and conditions applied by primary, community and hospital service providers.

The purpose of this policy is to:

- provide a clinical governance framework with clear lines of responsibility and accountability to support nurse and midwife medicinal product prescribing
- provide clear guidance, underpinned by the legislative and regulatory framework, to facilitate nurse and midwife medicinal product prescribing within health care settings
- ensure the safety of patients, clients, service users and all staff
- link the introduction and implementation of nurse and midwife medicinal product prescribing to strategic service planning
- ensure best practice with regard to nurse and midwife medicinal product prescribing
- support health service providers who are introducing and implementing nurse and midwife medicinal product prescribing
- develop more effective ways of working by providing better access and meeting patient/client/service user needs, in partnership and collaboration with the multidisciplinary team.

4.0 Scope

The scope of this policy relates to health service providers in the voluntary and statutory services of the HSE that have the required structures in place to support nurse and midwife medicinal product prescribing.

This policy applies to:

- registered nurse prescribers employed in voluntary and statutory services of the HSE, who have an authorised date from the director of nursing/midwifery/public health nursing, or relevant nurse or midwife manager (the Director) vesting them with prescriptive authority in a named area of practice and whose names appear on the register for nurse prescribers maintained by An Bord Altranais
- registered nurses and midwives in primary, community and hospital based services who are undertaking, or have undertaken, an approved education programme in Nurse and Midwife Medicinal Product Prescribing, or, are in the process of developing a collaborative practice agreement
- all key stakeholders supporting the introduction and implementation of nurse and midwife medicinal product prescribing in primary, community and hospital based services.

5.0 Glossary of Reference

- **Adverse [Drug] Reaction:** a response to a drug that is noxious and unintended and occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function (EEC Directive of 2001, [2001/83/EC]).
- **Authorised Medicinal Product:** a Medicinal Product which is authorised by the Irish Medicines Board (IMB) to be marketed in Ireland or by the European Commission (following assessment by the European Medicines Agency) for placing on the EU market. Such products have a product authorisation issued by the IMB (PA number) or, in the case of centrally authorised products an authorisation issued by the European Medicines Agency (EU Number) (An Bord Altranais, 2010). This was previously referred to as a 'licensed' medicinal product.
- **Authorised Medicinal Product prescribed for an Unauthorised Indication (formerly "Off-label"):** the use of an authorised medication outside the terms of its product authorisation, e.g. use for an indication, dose, specific patient population or specific age group which is not specified in the authorised product authorisation / summary of product characteristics (SmPC) (An Bord Altranais, 2010).
- **Brand (Proprietary) Name:** the trade name chosen by a manufacturer under which an active ingredient is marketed by them.
- **Candidate Nurse Prescriber:** a nurse or midwife whose name is entered on the Candidate Register of An Bord Altranais and is undertaking an approved programme of education and training leading to registration in the registered nurse prescribers division of the register or a nurse or midwife who has successfully completed the approved educational programme and is in the process of registering with An Bord Altranais (An Bord Altranais, 2007).
- **Clinical Governance:** This is a system through which service providers are accountable for continuously improving the quality of their clinical practice and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish (Scally and Donaldson 1998; HIQA, 2010; adapted HSE, 2010).
- **Clinical Indemnity Scheme (CIS):** The CIS was established in July 2002 and is managed by the State Claims Agency. Under the scheme the state assumes full responsibility for the indemnification and management of all clinical negligence claims against enterprises and practitioners covered by the scheme. CIS cover applies equally to the prescription/use of authorised medicinal products and authorised medicinal products prescribed for an unauthorised indication (formerly off-label) providing the latter is used with the expressed knowledge and consent of the enterprises management.
- **Collaborating Medical Practitioner(s):** the medical practitioner or group of medical practitioners with whom the registered nurse prescriber has a written collaborative practice agreement as part of the requirements to prescribe medicinal products within his/her scope of practice.
- **Collaborative Practice Agreement (CPA):** the CPA is drawn up with the agreement of the registered nurse prescriber, collaborating medical

practitioner and the employer outlining the parameters of the registered nurse prescriber's prescriptive authority (i.e. his/her scope of practice). The principles of professional accountability, responsibility, competence and clinical governance underpin the CPA. The medicinal products listing is approved by the Drugs and Therapeutics Committee and authorised by the director of nursing/ midwifery/public health nursing or relevant nurse/midwife manager on behalf of the health service provider (An Bord Altranais, 2012).

- **Competence:** the ability of a registered nurse prescriber to practice safely and effectively, fulfilling their professional responsibility within their scope of practice (An Bord Altranais, 2000).
- **Controlled Drug:** a substance which has the potential for abuse and is controlled under the Misuse of Drugs Acts 1977 and 1984 (<http://www.imb.ie/glossary>).
- **Drugs Payment Scheme (DPS):** Persons who are ordinarily resident in the state and who do not have a current Medical Card can benefit under the DPS. An individual or family has now to pay no more than the monthly threshold amount in a calendar month for approved drugs, medicines and appliances for themselves or their family. In order to benefit under this scheme, a person must register themselves and their dependents with their Local Health Office. DPS schemes are processed and paid by the Primary Care Reimbursement Service (PCRS).
- **Drugs and Therapeutics Committee:** this is a multidisciplinary advisory committee. The committee can provide expert advice and guidance to hospital or community-based staff on matters pertaining to the use of medicinal products, thus ensuring that prescribing and administration of medications are carried out in a safe and cost effective manner. The role of The Drugs and Therapeutics Committee in relation to nurse and midwife medicinal product prescribing within a health care setting involves approving the list of medicinal products, or categories, proposed in the collaborative practice agreement developed by the candidate or registered nurse prescriber and the collaborating medical practitioner/s. A Drugs and Therapeutics Committee must include (but is not restricted to) representation from senior nursing and midwifery personnel, senior medical personnel, pharmacist, and other expertise, for example clinical risk and general management. Throughout this document, Drugs and Therapeutics Committee also refers to a separate review group/committee established with terms of reference for the purpose of the nurse and midwife medicinal product prescribing initiative.
- **Education Provider:** an institution providing accredited education programmes in nurse and midwife medicinal product prescribing, which allows successful graduates to apply to register in the registered nurse prescribers' division of the register of nurses maintained by An Bord Altranais.
- **General Medical Services Scheme (GMS):** persons who are unable without undue hardship to arrange general practitioner, medical and surgical services for themselves and their dependants receive a free general medical service. Drugs, medicines and appliances supplied under the scheme are provided through retail pharmacies. All GMS

claims are processed and paid by the Primary Care Reimbursement Service (PCRS).

- **Generic Medicinal Product:** is a medicine which has the same active ingredient(s) as the brand name medicine and meets the same standards of safety, quality and effectiveness as the branded medicine.
- **Generic (non proprietary) name:** the name of the active ingredient of the medicine. Most generic names are the International Nonproprietary name (INN) a unique name that is globally recognised and is public property. The World Health Organisation (WHO) Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations advises the WHO on the selection of INNs.
- **Generic Prescribing:** a doctor or nurse prescriber prescribes a medicine using the generic (INN) name of its active ingredient.
- **Governance:** systems, processes and behaviour(s) by which organisations lead, direct and control their functions in order to achieve organisational objectives, safety and quality of service and in which they relate to patients/service users and carers, the wider community and partner organisations (Department of Health, 2006).
- **Health (Amendment) Act 1996 (HAA):** The Government has provided for the making available without charge of certain health services to certain persons who have contracted Hepatitis C, directly or indirectly from the use of Human Immunoglobulin Anti-D, or the receipt within the state of another blood product or blood transfusion. GP services, pharmaceutical services, dental services and optometric/ophthalmic services provided under the Act are paid for by the PCRS.
- **Health Service Provider:** the Health Service Executive, a hospital, a nursing home, a clinic or other person whose sole or principal activity or business is, the provision of health services or a class of health services, to the public or a class of the public. (Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations, 2007).
- **High Tech Drugs (HTD):** Arrangements are in place for the supply and dispensing of High Tech medicines through community pharmacies. Such medicines are generally only prescribed or initiated in hospital by a consultant and would include items such as anti-rejection drugs for transplant patients or medicines such as chemotherapy or growth hormones. The medicines are purchased by the HSE and supplied through community pharmacies for which pharmacists are paid a patient care fee. The cost of the medicines and patient care fees are paid by the PCRS.
- **Long Term Illness Scheme (LTI):** On approval by the HSE, persons who suffer from one or more of a schedule of illnesses are entitled to obtain, without charge, irrespective of income, necessary drugs/medicines and/or appliances under the LTI Scheme. LTI card holders are only approved for drugs relating to their long term illness. All LTI claims are processed and paid by the PCRS.
- **MDA-Controlled Drugs:** Misuse of Drugs (Amendment) Regulation, 2007 (<http://www.imb.ie/glossary>).
- **Medicinal Product:** any substance or combination of substances presented for treating or preventing disease in human beings. Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is

likewise considered a medicinal product (ECC Directive of 2001 [2001/83/EC]; An Bord Altranais, 2007).

- **Medication Error:** any preventable event that may cause or lead to inappropriate medication use or patient/client harm while the medication is in the control of the health care professional, patient/client encounter or consumer (An Bord Altranais, 2007).
- **Medical Mentor:** a consultant medical practitioner or general practitioner who has committed to act as a mentor and provide clinical instruction and supervision within the specific clinical practicum for the duration of the education programme (An Bord Altranais, 2007).
- **Near Miss:** this occurs where a medication error does not reach the patient/client/service user and no injury results (e.g. incorrect dosage is prescribed but is recognised and adjusted before the medication is administered) (An Bord Altranais, 2007).
- **Prescribe:** to authorise in writing the dispensing, supply and administration of a named medicinal product (typically a prescription-only medicine, but may include over-the-counter medications) for a specific patient/service user (An Bord Altranais, 2007).
- **Prescription:** prescription issued by a registered medical practitioner for the medical treatment of an individual, by a registered dentist for the dental treatment of an individual, by a registered veterinary surgeon for the purposes of animal treatment or by a registered nurse prescriber for the medical treatment of an individual subject to Article 3A of the Regulations (Misuse of Drugs (Amendment) Regulations 2007).
- **Prescribing Site Coordinator (PSC):** the person nominated by the director of nursing/midwifery/public health nursing or relevant nurse and midwife manager on behalf of the health service provider to be the prescribing liaison person. This person takes responsibility for the initiative locally, liaising with the education provider and the Office of the Nursing and Midwifery Services Director (team with responsibility for implementing the initiative).
- **Product Authorisation (PA):** A license to market a medicinal product granted by the Irish Medicines Board in accordance with Article 7 of the Medicinal Products (Licensing and Sale Regulations, 1998).
- **Primary Care Reimbursement Service (PCRS):** The PCRS is part of the HSE. PCRS supports the delivery of primary healthcare by providing reimbursement services to primary care contractors for the provision of health services to members of the public in their own community. PCRS is responsible for making payments to healthcare professionals, e.g. doctors, dentists and pharmacists, for the free or reduced costs services they provide to the public.
- **Registered Nurse Prescriber:** a nurse or midwife who is registered in the Division of the Register of Nurse Prescribers of An Bord Altranais (An Bord Altranais, 2007). 'Registered nurse prescriber' is used throughout this document to include nurse and midwife as this is the current legal description of a registered nurse or midwife with prescriptive authority.
- **Repeat Prescribing:** repeat prescribing may arise where the original issued prescription was issued by another prescriber and the patient/client/service user requests or requires a continued course of medication (An Bord Altranais, 2010).

- **Schedule 8:** The Misuse of Drugs (Amendment) Regulations, 2007 (S.I. 200 of 2007) details a new MDA schedule – Schedule 8 – which has been devised for the specific purpose of providing a detailed listing of the drugs, route of administration and condition for which Schedule 2 or 3 medication can be prescribed by the registered nurse prescriber. (Appendix 2) (Government of Ireland, 2007).
- **Summary of Product Characteristics:** The Summary of Product Characteristics forms the basis of prescribing information for healthcare professionals. Within the EU, the Summary of Product Characteristics (Abbreviated to SmPC and formerly known as the datasheet) forms part of the authorisation that a company must acquire for any medicine it wishes to market. In Ireland, the SmPC for each authorised product is available at <http://www.imb.ie>.
- **Unauthorised (exempt) medicine:** a medicinal product which does not carry either a Product Authorisation (PA) Number issued by the Irish Medicines Board (IMB) or a European Union (EU) authorisation number issued by the European Medicines Evaluation Agency. Authority to issue a prescription for an unauthorised medication does not extend to the registered nurse prescriber. This action is outside the nurse's and midwife's scope of practice for prescriptive authority. A patient/service user need for a prescription for an unauthorised medication should be referred to the appropriate medical practitioner (An Bord Altranais, 2010).

6.0 Roles and Responsibilities

These roles and responsibilities are only in relation to nurse and midwife medicinal product prescribing. The employing organisation must clearly differentiate between the functions of line management and clinical governance for nurse and midwife medicinal product prescribing. While these dual roles may be the responsibility of one person, there will be many instances when this is not the case. Where the registered nurse prescriber's direct line manager is not their professional nursing or midwifery support person, the organisation must clearly identify a senior nurse or midwife, either within or outside the organisation, to whom the registered nurse prescriber can refer for professional nursing or midwifery support and guidance. Where this is the case, this can be outlined in Attachment C of the CPA.

The following essential criteria must be put in place by the employing organisation in order to participate in nurse and midwife medicinal product prescribing. All of these supports may not necessarily be available to, or provided by, a single organisation. The combined resources of a number of organisations may be utilised to achieve the required criteria.

6.1 Regional Director of Operations/Area Manager

The Regional Director of Operations/Area Manager is responsible for:

- 6.1.1 ensuring that the vesting of prescriptive authority for nurses and midwives is included within the overall clinical governance structure of primary, community and hospital services and delegates responsibilities appropriately to relevant healthcare professionals
- 6.1.2 ensuring that arrangements are in place for the assessment of practice, clinical supervision, monitoring, audit and continuing professional development
- 6.1.3 identifying, in partnership with the Chief Executive Officer, General Manager, Clinical Director, Director of Nursing/Midwifery/Public Health Nursing or relevant nurse or midwife manager, the strategic direction of nurse or midwife medicinal product prescribing in their organisation and introduce the structures required for safe and appropriate prescribing.

6.2 The Director of Nursing/Midwifery/Public Health Nursing or Relevant Nurse Midwife Manager (Referred to Hereafter as The Director)

The Director is responsible for:

- 6.2.1 planning the strategic direction of nurse and midwife medicinal product prescribing in line with national and local policy direction
- 6.2.2 informing medical mentors and collaborating medical practitioners of their role in nurse and midwife medicinal product prescribing
- 6.2.3 signing the site declaration form on behalf of the respective health service provider and in so doing commits to ensuring that the following structures are in place to support nurse and midwife medicinal product prescribing:

Safe management

- the *National Policy for Nurse and Midwife Medicinal Product Prescribing* is in place
- an ability to safely manage and quality assure nurse and midwife medicinal product prescribing practices
- risk management systems and processes for adverse event reporting, incident reporting, reporting of near misses and reporting of medication errors

Practice and Education Development

- robust and agreed collaborative practice arrangements
- named medical practitioner/s who has/have agreed to develop the collaborative practice arrangements
- appropriate mentoring arrangements with a named mentor
- commitment to continuing education for registered nurse prescribers and also staff supporting the prescribing initiative
- the name of the nurse or midwife applying for the education programme is on the active register of nurses maintained by An Bord Altranais i.e. have current active registration
- have in place a sponsorship arrangement at local (service) level setting out the arrangements for study leave and financial support for the candidate

Health Service Provider

- access to a Drugs and Therapeutics Committee
- arrangements in place to oversee the introduction of a new practice in nurse and midwife medicinal product prescribing and ensure local evaluation of the implementation of the initiative
- a named individual with responsibility for the initiative locally and for liaison with the education provider, An Bord Altranais and the HSE Office of the Nursing and Midwifery Services Director team with responsibility for implementing the initiative. This person is known as the PSC
- a firm commitment by local management to support the introduction of nurse and midwife medicinal product prescribing
- commitment to comply with, and ensure data input, for the Nurse and Midwife Prescribing Data Collection System
- access to a computer, email and internet for data input to the Nurse and Midwife Prescribing Data Collection System
- share details of the registered nurse prescribers scope of practice and prescriptive authority with relevant health professionals.

Audit and Evaluation

- a mechanism to audit the nurse and midwife medicinal product prescribing practices.

6.2.4 The Director will also:

- be proactive in securing necessary resources for safe and effective nurse and midwife medicinal product prescribing
- appoint and support the PSC
- ensure that all entrants to the medicinal product prescribing education programme are selected according to criteria indicating their potential to prescribe safely in the area in which they will practice
- ensure the introduction of nurse and midwife medicinal product prescribing is in accordance with patient/client/service user needs and service demands
- identify a timeframe for submission of Attachment B of the collaborative practice agreement to The Drugs and Therapeutics Committee
- ensure timely review and renewal of the CPA
- maintain a record of registered nurse prescribers practising within their service area together with their collaborative practice agreements
- notify the registered nurse prescriber of a commencement date for prescriptive authority within their service area on receipt of confirmation of registration from An Bord Altranais
- ensure that arrangements are in place to provide access to continuing professional development for all registered nurse prescribers
- address identified breaches of the CPA and inform The Drugs and Therapeutics Committee and relevant stakeholders
- in cases where it is necessary to suspend the CPA the director will inform An Bord Altranais and all other relevant stakeholders
- provide reports pertaining to nurse and midwife medicinal product prescribing as required
- ensure the patient/client/service users are aware of the extended role of registered nurse prescribers

6.3 Line Manager of Candidate or Registered Nurse Prescriber

The Line Manager is responsible for:

- 6.3.1 in consultation with the interdisciplinary or multidisciplinary team and The Director, identifying the service need for nurse or midwife medicinal product prescribing
- 6.3.2 in consultation with The Director and PSC, identifying appropriate candidate/s to undertake the education programme (Nurse/Midwife Medicinal Product Prescribing) and supporting the application process
- 6.3.3 supporting the continuing professional development of the candidate/registered nurse prescriber
- 6.3.4 informing The Director of any breaches of the collaborative practice agreement and taking appropriate action
- 6.3.5 receiving, interpreting and responding appropriately to audit reports conducted on the registered nurse prescriber's

prescribing practice and providing feedback to the PSC as appropriate.

6.4 Prescribing Site Coordinator (PSC)

The PSC is responsible for the nurse and midwife medicinal product prescribing initiative as directed by The Director. This may involve:

- 6.4.1 coordinating the development, implementation, monitoring and evaluation of the structures and processes to support the implementation of safe nurse and midwife medicinal product prescribing
- 6.4.2 meeting the requirements of the health service provider and supporting its compliance with the requirements and standards of An Bord Altranais and the HSE
- 6.4.3 acting as a central point of contact for the candidate, registered nurse prescriber, mentor, collaborating medical practitioners and key stakeholders, and communicating all matters in relation to the nurse and midwife medicinal product prescribing initiative
- 6.4.4 liaising with candidates/registered nurse prescribers, the Drugs and Therapeutics Committee, The Director or relevant nurse/midwife manager, risk management, pharmacy department/pharmacist and all other relevant stakeholders
- 6.4.5 supporting registered nurse prescribers to meet their responsibilities to ensure safe and effective prescribing
- 6.4.6 facilitating the submission for approval to the Drugs and Therapeutics Committee by the candidate nurse prescriber, of the medicinal products listing within the completed CPA
- 6.4.7 supporting the registered nurse prescriber in the review and resubmission of the CPA
- 6.4.8 supporting and overseeing the implementation of the monitoring, audit and the evaluation processes for nurse and midwife prescribers in line with the health service provider audit policy
- 6.4.9 providing reports on the development, introduction, monitoring and evaluation of nurse and midwife medicinal product prescribing within the health service provider.

6.5 Potential Applicants

Potential applicants must:

- 6.5.1 ensure they are registered on the active register of nurses maintained by An Bord Altranais
- 6.5.2 comply with the Application Guidelines for the Education Programmes (HSE, 2011; <http://www.hse.ie/go/nurseprescribing>).

6.6 Candidate Nurse Prescriber

The candidate nurse prescriber must:

- 6.6.1 ensure he/she is registered on the candidate nurse prescriber register maintained by An Bord Altranais
- 6.6.2 comply with the sponsorship agreement setting out the local arrangements for study leave and financial support
- 6.6.3 successfully complete an approved education programme on Nurse /Midwife Medicinal Product Prescribing
- 6.6.4 ensure that the theoretical and clinical experience requirements and assessments are completed within the required timeframe
- 6.6.5 update the PSC on their progress on a regular basis
- 6.6.6 in consultation with the collaborating medical practitioner(s), complete the CPA and submit a medications listing to the Drugs and Therapeutics Committee having regard to relevant statutory provisions, professional guidance and health service provider policies pertaining to nurse and midwife medicinal product prescribing
- 6.6.7 discuss with the Director and the PSC any situations where these responsibilities cannot or are not being fulfilled.

6.7 Registered Nurse Prescriber

The Registered Nurse Prescriber has a responsibility to practice safely and commit to continuing professional development relating to assurance of competency for his/her prescribing practice (An Bord Altranais, 2010). The registered nurse prescriber must:

- 6.7.1 ensure his/her name is entered in the registered nurse prescribers division of the Register of Nurses maintained by An Bord Altranais
- 6.7.2 be responsible for the assessment of the patient/client/service user, making a diagnosis that may lead to a clinical decision to prescribe a medicinal product
- 6.7.3 hold full accountability and professional responsibility for all aspects of their prescribing practice and practice within a framework of professional accountability and legal boundaries as guided by the Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority (An Bord Altranais, 2010), the collaborative practice agreement and the organisational nurse and midwife medicinal product prescribing policy
- 6.7.4 demonstrate competencies for prescriptive authority encompassing:
 - professional and ethical practice
 - holistic approaches to care and integration of knowledge
 - interpersonal relationships
 - organisation and management of care
 - personal and professional development
- 6.7.5 commit to, and undertake, continuing professional development to maintain his/her competence for prescriptive authority
- 6.7.6 inform The Director, the line manager and the PSC of any concerns pertaining to his/her competence

- 6.7.7 integrate evidence-based knowledge relating to all aspects of medication management and actively seek learning opportunities (An Bord Altranais, 2007)
- 6.7.8 prescribe for patient/client/service user populations within the practice setting and scope of practice set out in the collaborative practice agreement
- 6.7.9 prescribe only for those patients/clients/service users whose medical practitioner is in agreement with prescriptive authority for nurses and midwives and their collaborative practice agreement
- 6.7.10 input information on all prescriptions written into the *Nurse and Midwife Prescribing Data Collection System* (Adams et al, 2010) and furnish statistical reports as required (at <https://www.nurseprescribing.ie>)
- 6.7.11 forward the completed review of the CPA to the Drugs and Therapeutics Committee and An Bord Altranais in accordance with An Bord Altranais requirements
- 6.7.12 maintain ongoing communication and collaboration with members of the health care team including collaborating medical practitioners, pharmacists and the PSC
- 6.7.13 work collaboratively with key stakeholders in order to enhance therapeutic outcomes for patients/clients/service users
- 6.7.14 act as an informed advisor to other candidates undertaking the nurse/midwife medicinal product prescribing programme
- 6.7.15 participate in audit and other quality assurance processes, including setting criteria for audit and self-audit where applicable (see section 11.3)
- 6.7.16 register with the Irish Medicines Board (IMB) in order to receive medication alerts and bulletins relating to medicinal products: www.imb.ie
- 6.7.17 routinely check for alert notices and bulletins issued by the Irish Medicines Board (IMB) (<http://www.imb.ie>) and the European Medicines Agency (EMA) website (<http://www.ema.europa.eu>)
- 6.7.18 inform An Bord Altranais, in writing, within five working days of the termination of a collaborative practice agreement and provide the reason for its termination (e.g. resignation or change of employment)
- 6.7.19 inform the drugs and therapeutics committee when a collaborative practice agreement is terminated
- 6.7.20 discuss with The Director and the PSC any situations where these responsibilities cannot, or are not being fulfilled.

6.8 The Medical Mentor

The Medical Mentor is responsible for:

- 6.8.1 availing of opportunities provided by the education providers, the health service providers and the Office of the Nursing and Midwifery Services Director to gain an understanding of the role of the mentor, e.g. publications, briefings, meetings
- 6.8.2 at the start of the education programme, exploring with the candidate their clinical learning needs and agreeing a programme/contract of learning. This is specific for each candidate, reflecting their differing clinical skills and experience
- 6.8.3 providing the candidate with supervision, support, teaching and learning opportunities equivalent to 12 days (96 hours) over the duration of the course. (Aspects of this learning may be delegated to other experienced members of the team or experts in the specialty/area)
- 6.8.4 providing learning opportunities and information updates necessary for evidence-based medicinal product prescribing practices
- 6.8.5 meeting formally with the candidate at three and six months to review progress
- 6.8.6 formally assessing the candidate prescriber's progress in the clinical setting using the assessment tool provided by the third level institution (e.g. Objective Structured Long Examination Record (OSLER))
- 6.8.7 at the end of the education programme, completing and 'signing off' the candidate's Competency Booklet/Mentor Declaration
- 6.8.8 medical mentors who are General Practitioners and therefore not covered by the Clinical Indemnity Scheme, inform their insuring body that they are supporting nurse/midwife medicinal product prescribing.

6.9 The Drugs and Therapeutics Committee

- 6.9.1 This committee is responsible for reviewing and approving the medicinal products listing (attachment B of the CPA) put forward for nurse and midwife medicinal product prescribing by the candidate nurse prescriber/registered nurse prescriber and the collaborating medical practitioner(s). It is not necessary for the Drugs and Therapeutics Committee to review attachments A and C of the CPA. However, this may be required by some Drugs and Therapeutics Committees for clarity and context.
- 6.9.2 Some health service providers may not have an established Drugs and Therapeutics Committee. But instead there is a review group or committee established with specific terms of reference for the nurse and midwife medicinal product prescribing initiative in the organisation. The responsibilities of this group or committee include the approval of the medications listed in Attachment B of the Collaborative Practice Agreement.

- 6.9.3 The following points should be considered when developing terms of reference for the Drugs and Therapeutics Committee in respect of nurse and midwife medicinal product prescribing:
- ensure that the medicinal products listing complies with all relevant statutory provisions, professional guidance and health service provider policies
 - advise, where relevant and appropriate, on any additional conditions to be applied to the registered nurse prescriber's prescriptive authority in the specific health service provider
 - approve any changes to the medicinal product listing agreed between the collaborating medical practitioner/s and the registered nurse prescriber
 - approve the medicinal products listing following the review of the CPA as per An Bord Altranais timelines for the renewal process
 - if in line with local terms of reference or local policy, review the report of the audit and activity of the registered nurse prescriber's medicinal product prescribing practice
 - advise in the event of a dispute or breach of the medicines listing (attachment B of the collaborative practice agreement).

6.10 The Collaborating Medical Practitioner(s)

- 6.10.1 Where the patient/client/service user cohort involves either one or a number of medical practitioners, the responsibilities of the Collaborating Medical Practitioner(s) are as follows:
- support the introduction of nurse and midwife medicinal product prescribing
 - be in agreement with the list of medicinal products named in the CPA and any conditions pertaining
 - agree communication and referral mechanisms with the registered nurse prescriber
 - give their written approval/signature for the collaborative practice agreement.
- 6.10.2 Where a registered nurse prescriber has a collaborative practice agreement with a group GP practice, the lead GP in the practice may discuss nurse and midwife medicinal product prescribing with their colleagues and, with their approval, may sign on behalf of the practice. The lead GP has the responsibility to inform GPs/locums of the practice's commitment to nurse and midwife prescribing.
- 6.10.3 Where a registered nurse prescriber has a collaborative practice agreement with a number of medical practitioners, the lead practitioner may discuss nurse and midwife medicinal product prescribing with their colleagues and, with their approval, may sign on behalf of the others. The lead practitioner has the responsibility to inform the other practitioners/locums of the organisation's commitment to nurse and midwife medicinal product prescribing. A listing of all collaborating medical practitioners must be maintained by the health service provider.

- 6.10.4 The collaborating medical practitioner(s) should be aware of the professional regulatory and health service provider requirements for the registered nurse prescriber's continuing competence for maintaining medicinal product prescriptive authority.
- 6.10.5 The collaborating medical practitioner(s) will report any dispute with, or breach of, the CPA to the line manager and then to the Director or as per local policy.
- 6.10.6 Where possible, the collaborating medical practitioner(s) participate(s) in the monitoring and auditing of registered nurse prescriber's medicinal product prescribing practice.

6.11 The Pharmacist

- 6.11.1 The provision of information and advice by pharmacists is important in promoting evidence-based high quality prescribing, which is a key objective of nurse and midwife prescribers, pharmacists and all prescribers.

7.0 Eligibility to Prescribe

7.1 Conditions

The health service provider may identify certain conditions that the nurse or midwife must adhere to in order to prescribe. This may include a listing of all local policies, protocols and guidelines that staff must adhere to in implementing prescriptive authority for nurses and midwives, e.g. medication management or abbreviations. In addition to these conditions, and in order to attain authority to prescribe, the following stipulations must be adhered to:

- 7.1.1 the candidate nurse prescriber must have successfully completed the accredited education programme
- 7.1.2 the registered nurse prescriber's name must be entered on the Division of the Register of Nurse Prescribers maintained by An Bord Altranais
- 7.1.3 the registered nurse prescriber must be employed by the health service provider
- 7.1.4 the registered nurse prescriber must have an agreed valid written collaborative practice agreement with the medical practitioner/s
- 7.1.5 the registered nurse prescriber must have received formal notification of the commencement date for prescriptive authority from The Director, on behalf of the health service provider before commencing prescribing
- 7.1.6 the registered nurse prescriber must have a full understanding of the requirements of the nurse or midwife medicinal product prescribing policy of the health service provider
- 7.1.7 in the event that a registered nurse prescriber wishes to discontinue a medicinal product which was prescribed by another prescriber, the decision making process, rationale and indication for the discontinuation should be clearly documented. Where appropriate, the discontinuation should be discussed with the original prescriber as soon as possible.

7.2 Validation of the Collaborative Practice Agreement and Registration with An Bord Altranais

Prescriptive authority for the registered nurse prescriber extends only to those medicinal products normally used in the named clinical area, listed in the collaborative practice agreement, approved by the collaborating medical practitioner and authorised by The Director.

- 7.2.1 The candidate nurse prescriber must prepare the collaborative practice agreement in consultation with the collaborating medical practitioner(s) in accordance with An Bord Altranais guidelines.
- 7.2.2 The candidate nurse prescriber must ensure that all sections and attachments of the CPA are correctly completed and fully edited prior to forwarding to the Drugs and Therapeutics Committee and the Director.
- 7.2.3 The list of medicinal products that will be prescribed by the registered nurse prescriber is forwarded to the Drugs and Therapeutics Committee for review and approval (Attachment B of the CPA).

- 7.2.4 When the list of medicinal products has been reviewed by the Drugs and Therapeutics Committee, the PSC or candidate nurse prescriber, forwards a copy of the signed collaborative practice agreement, including attachment A, B, and C to The Director for authorisation.
- 7.2.5 The Director, on behalf of the health service provider, then authorises and signs the collaborative practice agreement.
- 7.2.6 The candidate nurse prescriber submits the following to An Bord Altranais to have their name entered in the Division of Registered Nurse Prescribers:
- the relevant documentation in relation to the completed CPA
 - the completed signed and stamped *Application Form for Registration in the Registered Nurse Prescribers' Division of the Register*
 - the relevant registration fee.
- 7.2.7 Confirmation letters of registration as a registered nurse prescriber are then sent to the individual nurse or midwife and to their employer by An Bord Altranais.
- 7.2.8 The Director, on behalf of the health service provider, informs the registered nurse prescriber, in writing, of the commencement date on which they are authorised to start prescribing.
- 7.2.9 Original copies of the collaborative practice agreement and copies of registration are maintained in the nurse or midwife's personnel file. The nurse or midwife should also retain a copy of the complete CPA, including attachments A, B and C.
- 7.2.10 The CPA is reviewed according to An Bord Altranais guidelines by the registered nurse prescriber and collaborating medical practitioner(s). Changes should be based on the registered nurse prescriber's scope of practice in relation to attainment of competency and confidence to assess, diagnose and treat health conditions. Changes should also be based on patient/client/service user need as well as service need.
- 7.2.11 Changes to Attachment B of the CPA must be reviewed and approved by the Drugs and Therapeutics Committee.
- 7.2.12 Any changes to the CPA must be authorised by the health service provider.

7.3 Termination of the Collaborative Practice Agreement

- 7.3.1 The collaborative practice agreement is terminated if the registered nurse prescriber or the collaborating medical practitioner/s resigns from their post. Where there is more than one collaborating medical practitioner, the CPA is valid with those remaining.
- 7.3.2 The collaborative practice agreement will be deemed invalid and no longer enforceable on the termination, transfer or movement by the RNP from the post for which it was originally developed.
- 7.3.3 The collaborative practice agreement is subject to review, suspension and possible termination if the registered nurse prescriber, or collaborating medical practitioner, is subject to

disciplinary action or fitness to practice review by their regulatory body.

7.3.4 The collaborative practice agreement terminates automatically if the registered nurse prescriber or medical practitioner no longer has an active unrestricted registration.

7.3.5 In the event of a termination of a collaborative practice agreement, the registered nurse prescriber will notify in writing the Director and An Bord Altranais, within five working days of the termination and also provide the reason/s for its termination (for example, resignation or change of employment).

8.0 Clinical Indemnity

8.1 The State Claims Agency Clinical Indemnity Scheme

The Clinical Indemnity Scheme (CIS) was established in July 2002 and is managed by the State Claims Agency. Under the scheme, the state assumes full responsibility for the indemnification and management of all clinical negligence claims against enterprises and practitioners covered by the scheme (Appendix D).

- 8.1.1 Registered nurse prescribers are individually and professionally accountable to An Bord Altranais and their employer for all decisions pertaining to their medicinal product prescribing practice.
- 8.1.2 The State Claims Agency has issued a statement in relation to clinical indemnity in respect of nurse or midwife medicinal product prescribing in the public health services - please refer to Appendix D for details of cover provided for all clinical practitioners.
- 8.1.3 The State Claims Agency has issued a statement in respect of clinical indemnity in relation to unauthorised (exempt) and authorised medicines prescribed for an unauthorised indication (off-label) (Appendix E).
- 8.1.4 Collaborating medical practitioners or mentors who are General Practitioners are not covered by this scheme and therefore should inform their insuring body that they are supporting nurse or midwife medicinal product prescribing and that appropriate indemnity cover is in place.

9.0 Community Drug Prescribing Schemes

The issue of Circular SO222-NCO-09 outlined that the policy decision was that certain community registered nurse prescribers, employed by the HSE, would be issued with a pad of Primary Care Prescription Forms with their own allocated GMS number. This encompassed the GMS, DPS, LTI and HAA prescribing schemes.

9.1 Primary Care Prescription Form

- 9.1.1 Circular number 013/11 sets out the arrangements for certain community registered nurse prescribers to be issued with Primary Care Prescription Forms. The registered nurse prescriber's GMS number will be allocated once the Primary Care Reimbursement Service (PCRS) has been notified that the registered nurse prescriber is authorised by the HSE employer to commence prescribing.
- 9.1.2 Specific criteria will apply to the decision to issue certain community registered nurse prescribers with a Primary Care Prescription Pad
- 9.1.3 In order to be issued with a Primary Care Prescription Pad, the registered prescriber must download *The Application Form*

Notification and Authorisation of the Community Registered Nurse Prescriber from <http://www.hse.ie/go/nurseprescribing>.
(See Appendix F for the application form and process).

10.0 Procedure

10.1 The Clinical Decision-Making Process

As a registered nurse prescriber, the nurse or midwife takes responsibility for their own prescribing decisions. The registered nurse prescriber is required to:

- 10.1.1 be accountable for their prescribing decisions, including acts or omissions, and cannot delegate this decision to any other person
- 10.1.2 prescribe only for patients/clients/service users where they have undertaken a clinical assessment
- 10.1.3 be aware of patient/client/service user's full list of current medication at the time of prescribing
- 10.1.4 when appropriate, use laboratory, radiological and other diagnostic tests in order to reach a sound clinical diagnostic decision
- 10.1.5 make appropriate treatment decisions, based on consultation and assessment of each individual patient/client/service users needs (and the family or carer where appropriate)
- 10.1.6 consider an overall treatment plan, taking cognisance of the treatment decisions of other health care professionals
- 10.1.7 be alert to possible adverse effects and drugs interactions. Information regarding possible adverse effects and drug interactions can be found in the SmPC for the product concerned. Additional information, if required to enable appropriate drug treatment decisions, can be obtained from the National Medicines Information Centre (NMIC) via its query answering service
- 10.1.8 recognise the limits of his/her scope of practice and consult with and/or refer to medical staff and other health care professionals where indicated.

10.2 Communication, History Taking and Documentation

Comprehensive history taking and consultation with the patient/client/service user are fundamental principles of safe and effective prescribing practice. It is the responsibility of the registered nurse prescriber to document and communicate the prescribing consultation in accordance with An Bord Altranais Practice Standards and Guidelines (2010).

- 10.2.1 The responsibility for prescriptive authority requires the registered nurse prescriber to communicate effectively with the patient/client/service user and other health care professionals involved in their care.
- 10.2.2 Registered nurse prescribers must ensure that the patients / clients / service users and / or, where appropriate, family members/significant others, are aware that they are being treated by a nurse or midwife prescriber. The registered nurse prescriber may provide the patient / client / service user with the patient information leaflets, Nurse and Midwife Prescribers – How they care for you (2008) and also Nurse Prescribing and Your Child, Information for Parents, Carers and Guardians (Health Service Executive, 2010). These can be downloaded at <http://www.hse.ie/go/nurseprescribing> or, for multi-lingual patient

information leaflets,
http://www.hse.ie/eng/services/find_a_service/languages.

- 10.2.3 The registered nurse prescriber should document assessment, treatment, review and follow-up plan of care in the patient/client/service user's health care record, maintaining acceptable standards of recording clinical practice (An Bord Altranais, 2010).
- 10.2.4 Patients/clients/service users (and their families if appropriate) should be involved in treatment decisions and informed about the medications prescribed including the purpose of the medication, the route of administration, the duration of treatment, possible side-effects and any other relevant issues.
- 10.2.5 Decisions in relation to prescribing of medications should be communicated to other members of the healthcare team as soon as is practical ensuring that a continuing care plan or discharge plan is completed for the patient/client/service user.
- 10.2.6 The Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority (An Bord Altranais, 2010) should be used as a guide for documenting and communicating prescribing decisions.

10.3 Guidance for Prescription Writing in Practice

Registered nurse prescribers must comply with their health service provider's prescribing policy for all prescribers. The registered nurse prescriber must use an approved health service provider / organisation prescription pad / prescription chart / primary care prescription form to write prescriptions.

- 10.3.1 Specific standards for prescription writing must be adhered to as required by legislation, professional guidelines and the service/organisation policy.
- 10.3.2 The registered nurse prescriber must undertake an appropriate assessment of the need for treatment prior to writing a prescription.
- 10.3.3 It is not permitted to write prescriptions for oneself, family or significant others. In the event of a possible blurring of the professional and personal boundaries of care, the individual requiring a prescribed medication should be referred to another appropriate prescriber.
- 10.3.4 The registered nurse prescriber is not authorised under any circumstances to issue a prescription either verbally, by telephone, email or fax.
- 10.3.5 A registered nurse prescriber may not issue a prescription for unauthorised medication.
- 10.3.6 Prescription writing should concur with the Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority (An Bord Altranais, 2010).
- 10.3.7 The prescription should contain the full name and address of the patient/client/service user. If under 12 years of age, include the date of birth.
- 10.3.8 It is recommended that the generic or non-proprietary name of the medication be used on the prescription. However, it is

- acknowledged that with some medications the proprietary name may need to be used.
- 10.3.9 It is good practice to identify the maximum daily dose of the medication.
- 10.3.10 When recording the strength or dosage of the medication it is recommended that only internationally and nationally accepted abbreviations be used (Health Service Executive, Code of Practice for Healthcare Records Management: Abbreviations, 2010).
- 10.3.11 Doses should follow normal convention, i.e. g for grams, mg for milligrams. Micrograms and nanograms should be written in full.
- 10.3.12 The registered nurse prescriber should be cognisant of the intended or appropriate duration of treatment and the classification of medicines under the *Medicinal Products (Prescription and control of Supply) (Amendment) Regulations, 2007 (SI 201 of 2007)*.
- 10.3.13 Prescriptions must be dated and signed by the registered nurse prescriber with their usual full signature and must include the Personal Identification Number (PIN) from An Bord Altranais.
- 10.3.14 Corrections cannot be made to a prescription once written, the prescription must be re-written. Use of correction fluid or deleting with a pen is not permitted.
- 10.3.15 It is important to ensure that the instructions regarding the medications are understood and agreed by the patient/client/service user.

10.4 Prescription Writing for Schedule 8 - Controlled Drugs

The Misuse of Drugs (Amendment) Regulations, 2007, clearly documents the particular requirements that must be met for a registered nurse prescriber to issue a prescription for Schedule 2 or 3 MDA drugs. A new MDA schedule, Schedule 8, has been devised for the specific purpose of providing a detailed listing of the drugs, route of administration and conditions for which the Schedule 2 or 3 medications can be prescribed by the registered nurse prescriber (Appendix C).

- 10.4.1 Prescription writing for MDA-controlled drugs must adhere to Schedule 8 of the *Misuse of Drugs (Amendment) Regulations 2007*.
- 10.4.2 The registered nurse prescriber has no legal authority to prescribe any other Schedule 2 or 3 controlled drugs which are not listed on Schedule 8.
- 10.4.3 For medicinal products listed on Schedule 8, the registered nurse prescriber may not prescribe for a different route of administration of the named drug, nor prescribe for any other condition or situation not named in the Schedule 8 list (Appendix C).
- 10.4.4 Schedule 8 - Controlled Drugs cannot be prescribed by the registered nurse prescriber unless they are authorised to do so in their collaborative practice agreement.
- 10.4.5 In addition to the prescription writing requirements outlined in section 10.3, the registered nurse prescriber must handwrite:
- the name and address of the patient/client/service user
 - the dose to be prescribed

- the form (in the case of preparations)
 - the strength
 - either the total quantity (in both words and figures) of the drug or preparation, or the number (in both words and figures) of dosage units to be supplied
 - ensure that the prescription clearly states: the nurse or midwife's prescriber's address, the telephone number at which he/she can be contacted
 - their full signature in their usual handwriting
- 10.4.6 A prescription for Schedule 8 - Controlled Drugs cannot be repeated but may be dispensed in installments by the direction of the registered nurse prescriber.
- 10.4.7 A Schedule 8 prescription is only valid for 14 days from date of issue.

10.5 Separation of Responsibilities in the Medication Management Cycle

- 10.5.1 It is advisable that the registered nurse prescriber should not undertake to prescribe and supply or to prescribe and administer a medication as part of an episode of care. Another registered nurse or midwife should undertake the administration of the medicine.
- 10.5.2 In cases where it is necessary for the registered nurse prescriber to undertake to prescribe and administer a medication, the reason for this decision should be clearly documented. Where possible, a second independent check of the medication should be carried out. The CPA (Attachment C) must clearly outline when such instances are acceptable and also provide for the auditing of these practices as part of the overall audit of nurse and midwife prescriptive practice.
- 10.5.3 In specific circumstances, where the registered nurse prescriber may be required to supply a medicine, the prescriber should be aware of his/her responsibilities with this practice in the overall management of medication. Whilst recognising the separation of responsibilities for prescribing and supplying medication as a fundamental principle, the local site specific CPA should outline situations where the registered nurse prescriber may, in fact, be involved in a cross-over and merging of these activities as part of the provision of patient/client/service user care. The CPA should provide for the auditing of such practices as part of the overall audit of prescriptive practices (An Bord Altranais, 2010).

10.6 Repeat Prescribing

- 10.6.1 Repeat prescribing may arise in situations, (commonly chronic health conditions), where the original prescription was issued by the registered nurse prescriber, or another prescriber, and the patient/client/service user requires a continued course of medication.
- 10.6.2 In instances of repeat prescribing for continued treatment, the registered nurse prescriber must undertake an appropriate assessment of the need for continued treatment with the prescribed medication.

- 10.6.3 The decision-making process should be documented, including details of discussions with the patient/client/service user, (and if appropriate, family or carer), regarding perceived effectiveness, adherence to treatment and plans for review.
- 10.6.4 Where appropriate, the registered nurse prescriber should discuss his/her decision to repeat the prescription with the original prescriber as soon as is practical.
- 10.6.5 The registered nurse prescriber should acknowledge their scope of practice for prescribing, recognising any limitation of competence or knowledge and make appropriate referrals where indicated.
- 10.6.6 The registered nurse prescriber should be cognisant of the intended or appropriate duration of treatment and the classification of medicines under the *Medicinal Products (Prescription and control of Supply) (Amendment) Regulations, 2007 (SI 201 of 2007)*.

10.7 Prescribing of Unauthorised Medicinal Products and Authorised Medicinal Products Prescribed for an Unauthorised Indication (Off-Label)

- 10.7.1 **Unauthorised (unlicensed) medicinal products:** Medicinal Products, *(Control of Placing on the Market) Regulations (2007-2010)*, provide statutory authority for a medical practitioner to treat a patient under his/her care, using unauthorised (unlicensed) medicinal products. This authority does not extend to registered nurse prescribers.
- 10.7.2 **Authorised (licensed) medicinal products prescribed for an unauthorised indication (Off-Label):** it is not prohibited in the relevant legislation and regulations for a registered nurse prescriber to issue a prescription for an authorised (licensed) medicinal product in respect of an unauthorised clinical indication (i.e. Off-Label indication). This is in accordance with Regulation 5A of the *Medicinal Products (prescription and control of supply) regulations, 2003* as amended. Registered nurse prescribers should give careful consideration to decisions to prescribe a medication for an unauthorised indication, particularly having regard to the clinical appropriateness of the 'Off-Label' use and whether an alternative product is authorised to treat that indication.
- 10.7.3 The registered nurse prescriber should be knowledgeable in relation to best practice for prescribing an authorised medication for an unauthorised indication. This includes determining:
 - if there is an alternative authorised (licensed) medication that could be prescribed
 - if the medication is regularly used to treat patient/client/service users in the registered nurse prescriber's area of clinical practice
 - that the listing of the specific medication is within the health service provider's prescribing formulary and/or guidelines
- 10.7.4 The registered nurse prescriber should refer to the document, *Medicinal Product Authorisation, Information and Frequently Asked Questions for Registered Nurse Prescribers* (Office of the Nursing and Midwifery Services Director, 2011) for further support, when

including off-label medications on Attachment B of their CPA. This can be downloaded from <http://www.hse.ie/go/nurseprescribing>.

- 10.7.5 The HSE has developed a template (Appendix G) for the statutory and voluntary services of the HSE to assist decision-making in authorising a registered nurse prescriber to prescribe an authorised medicinal product prescribed for an unauthorised indication (Off-Label). The template can be downloaded from <http://www.hse.ie/go/nurseprescribing>.

10.8 Security and Safe Handling of Prescription Pads

- 10.8.1 Prescription pads are the property of the respective employing health service provider and should be stored securely. The registered nurse prescriber should ensure that prescription pads are stored in a secure place under lock and key when not in use.
- 10.8.2 The registered nurse prescriber should report promptly any loss or theft of prescription pads (or sections/pages of the prescription pads) to their line manager, relevant pharmacists, medical practitioners and, where applicable, PCRS and complete a risk management occurrence form/incident form.
- 10.8.3 The registered nurse prescriber, reporting the loss, should verify (where possible) the serial number and identify the number of unused prescription sheets remaining in the pad.
- 10.8.4 The Director, or designated person, on behalf of the health service provider, should report any such incident to the Garda Síochána.

10.9 Adverse Drug Reactions

- 10.9.1 Registered nurse prescribers should undertake to keep up to date with all prescribing information of the medicinal products they prescribe including up-to-date safety information.¹
- 10.9.2 If an adverse drug reaction associated with the use of a medicine occurs during or following the administration of any medicinal preparation, administration of the medicinal preparation **should cease immediately** and the following take place:
- the registered nurse prescriber or relevant nursing or midwifery staff should remain with the patient and closely monitor for all adverse reactions
 - vital signs should be recorded
 - the relevant medical practitioner should be informed immediately and the patient/client/service user should be reviewed by a medical practitioner
 - the adverse drug reaction and all relevant nursing or midwifery and medical management and interventions must be recorded promptly
 - the patient/client/service user (and/or family/carers where appropriate) should be informed of what has happened by

¹ The Irish Medicines Board Publications, British National Formulary (BNF) and Irish National Formulary articles, drug safety newsletters, and the outcomes of EU safety reviews, new product warnings, details of recalls/suspensions, SmPCs and package leaflets are provided via e-mail or text message to prescribers registered with the IMB. To register for electronic alerts, logon to <http://www.imb.ie> and follow the link: *Subscribe to our Updates*

- the registered nurse prescriber or relevant nursing or midwifery and/or medical staff
 - where available, all vials, ampoules, infusions and remaining batch of medicinal preparations should be retained in accordance with local guidelines.
- 10.9.3 The registered nurse prescriber must report any suspected adverse drug reactions to the relevant medical practitioner, the pharmacy department/dispensing pharmacist and the clinical risk manager in line with local policy/guidelines.
- 10.9.4 The registered nurse prescriber should report to the IMB any suspected adverse drug reactions, in accordance with criteria outlined by the IMB. This includes any suspected adverse drug reactions brought to the attention of the registered nurse prescriber. Reporting of the suspected adverse drug reaction may be carried out on line at <http://www.imb.ie> or through use of the yellow card system. This system is available in a downloadable format from the IMB website, or, on request from the IMB. Copies of reporting forms are also available in the British National Formulary (BNF), but should be sent to the IMB.
- 10.9.5 The registered nurse prescriber may advise patients/clients/service users that they can submit a report to the IMB on any adverse drug reactions that may occur.

10.10 Medication Errors/Near Misses

- 10.10.1 In the case of medication errors or near misses that may directly involve the patient / client / service user, i.e. wrong medication / dose / route being prescribed or administered, or another prescribing error, the registered nurse prescriber or nursing or midwifery staff must remain with the patient/client/service user and closely monitor the patient/client/service user for any adverse reactions.
- 10.10.2 Vital signs should be recorded and the patient/client/service user should be reviewed as soon as possible by the medical practitioner.
- 10.10.3 The incident must be reported to the line manager as soon as possible.
- 10.10.4 If deemed necessary, the National Poisons Information Centre in Beaumont Hospital should be contacted at **+353 (0)1 809 2566/+353 (0)1 837 9964**.
- 10.10.5 The incident and all actions taken must be promptly and clearly recorded in the relevant health care record.
- 10.10.6 The patient/client/service user (and family or carer where appropriate) must be informed of the incident.
- 10.10.7 A risk management occurrence form (incident report/medication error/near miss form) must be completed and sent to the relevant member of staff (The Director or relevant nurse/midwife manager) and risk management department in accordance with individual health service provider policy. Local reporting guidelines must be followed.
- 10.10.8 Any suspected adverse drug reactions associated with medication errors should be reported to the IMB as outlined in 10.9.4.

11.0 Monitoring and Audit

11.1 Verification of Prescribing Status

- 11.1.1 An aspect of monitoring is to verify that the nurse or midwife prescriber is registered appropriately with An Bord Altranais. It is possible for health professionals and the general public to verify the prescribing status of each registered nurse prescriber by checking the Nurses Register by one of the following two methods:
- logging onto <http://www.nursingboard.ie> and going to the 'check the register' tab at the top right of the homepage. After the name and/or personal identification number (PIN) of the nurse or midwife is entered, the registration information returned for the individual nurse or midwife can be reviewed
 - telephoning An Bord Altranais at +353 (1) 6398500 (centre) to request a check for the nurse or midwife's registration
 - registered nurse prescribers on the division of the register of nurse prescribers will have their CPA status identified.

11.2 Monitoring Nurse and Midwife Medicinal Product Prescribing

- 11.2.1 The registered nurse prescriber must enter all prescriptions onto the Nurse and Midwife Prescribing Data Collection System (available at <https://www.nurseprescribing.ie>).
- 11.2.2 Reports from the system can be generated by registered nurse prescribers, PSCs and The Directors and used to monitor the prescribing activity within their organisation.
- 11.2.3 Identified person/s within each organisation should determine the frequency of reports required and the personnel to whom they should be submitted.
- 11.2.4 For guidance and support in relation to the data collection system, refer to chapter four of the *Guiding Framework for the Implementation of Nurse and Midwife Prescribing in Ireland* (Office of the Nursing Service Director, 2008).

11.3 Audit of Nurse and Midwife Medicinal Product Prescribing

- 11.3.1 The specific health service provider, in collaboration with the registered nurse prescriber, will agree and define the criteria for audit including the mechanism, the personnel involved, the frequency and the reporting requirements.
- 11.3.2 Chapter 5 and Appendices 16, 17 and 18 (Pages 151, 155 and 159) of the *Guiding Framework for the Implementation of Nurse and Midwife Prescribing in Ireland* (Office of the Nursing Services Director, 2008) sets out the HSE recommendations in relation to the audit of nurse/midwife prescribing. Chapter 6 and Appendix 2 of the *National Independent Evaluation of Nurse and Midwife Prescribing Initiative* (Drennan et al, 2009) describes the process used for audit of nurse and midwife medicinal product prescribing including the use of the *medication appropriateness index tool*.

There is a requirement in Attachment C of the CPA to 'outline the requirement for review and audit of registered nurse prescriber's prescriptive practices' (available at <http://www.nursingboard.ie>).

- 11.3.3 Reports from the Nurse and Midwife Prescribing Data Collection System can be used as a data source to inform the audit process.

Reference List

- Adams, L., Cuddy, A., Flynn, M., Lorenz, R. and MacGabhann, C. (2010) Nurse and Midwife Prescribing in Ireland: the Minimum Data Set. *Nurse Prescribing*. 8 (5): 234-241
- An Bord Altranais (2012) *Collaborative Practice Agreement for Nurses and Midwives with Prescriptive Authority*. 3rd Edition. Dublin: An Bord Altranais
- An Bord Altranais (2010) *Nurses Rules 2010*. Dublin: An Bord Altranais
- An Bord Altranais (2010) *Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority*. 2nd Edition. Dublin: An Bord Altranais.
- An Bord Altranais (2010) *Practice Standards for Midwives*. Dublin: An Bord Altranais
- An Bord Altranais (2009) *Professional Guidance for Nurses working with Older People*. Dublin: An Bord Altranais
- An Bord Altranais (2007) *Decision Making Framework for Nurses and Midwives with Prescriptive Authority*. Dublin: An Bord Altranais
- An Bord Altranais (2007) *Guidance to Nurses and Midwives on Medication Management*. Dublin: An Bord Altranais
- An Bord Altranais (2007) *Requirements and Standards for Education Programmes for Nurses and Midwives with Prescriptive Authority*. Dublin: An Bord Altranais
- An Bord Altranais (2002) *Recording Clinical Practice Guidance to Nurses and Midwives*. Dublin: An Bord Altranais
- An Bord Altranais (2000) *The Code of Professional Conduct for Each Nurse and Midwife*. Dublin: An Bord Altranais
- An Bord Altranais (2000) *Review of Scope of Practice for Nursing and Midwifery: Final Report*. Dublin: An Bord Altranais
- Department of Health and Children (2011) *Strategic Framework for Role Expansion of Nurse and Midwife: Promoting Quality Patient Care*. Dublin: Stationery Office
- Department of Health and Children (2009) *Children First: National Guidelines for the Protection and Welfare of Children*. Dublin: Stationary Office
- Department of Health and Children (2006) *Integrated Governance Handbook: A Handbook for Executives and Non-executives in Healthcare Organisations*. London: Stationery Office
- Department of Health and Children (2005) *National Disability Strategy*. Dublin: Stationery Office
- Department of Health and Children (2006) *Vision for Change: Report of the Expert Group on Mental Health*. Dublin: Stationery Office
- Department of Health and Children (2001) *Primary Care: A New Direction*. Dublin: Stationery Office
- Department of Health and Children (2001) *Quality and Fairness: A Health System For You*. Dublin: Stationery Office

Drennan, J., Naughton, C., Allen, D., Hyde, A., Felle, P., O'Boyle, K., Tracey, P., Butler, M. (2009) *Independent Evaluation of the Nurse and Midwife Prescribing Initiative*. Dublin University College: Dublin (available at www.hse.ie/go/nurseprescribing)

Government of Ireland (2009) *IMB (Miscellaneous Provisions) Act 2006 (Commencement) Order Statutory Instrument No 67 of 2009*. Dublin: Stationery Office (available at <http://www.irishstatutebook.ie>)

Government of Ireland (2008) *Building a Culture of Patient Safety: Report of the Commission on Patient Safety and Quality Assurance*. Dublin: Stationery Office

Government of Ireland (2007) *Medicinal Products (Control of Placing on the Market) Regulations, 2007-2010*. Dublin: Stationery Office (available at <http://www.irishstatutebook.ie>)

Government of Ireland (2007) *(Miscellaneous Provision) Act 2006 (Commencement) Order 2007*. Dublin: Stationery Office (available at <http://www.irishstatutebook.ie>)

Government of Ireland (2007) *(Miscellaneous Provision) Act 2006 (No. 3 of 2006) (Section 10(1(ii)))*. Dublin: Stationery Office (available at <http://www.irishstatutebook.ie>)

Government of Ireland (2007) *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007, Statutory Instruments No. 201 of 2007*. Dublin: Stationery Office (available at <http://www.irishstatutebook.ie>)

Government of Ireland (2007) *Misuse of Drugs (Amendment) Regulations 2007, Statutory Instruments No.200 of 2007*. Dublin: Stationery Office (available at <http://www.irishstatutebook.ie>)

Government of Ireland (2001) *Mental Health Act, Number 25 of 2001*. Dublin: Stationery Office (available at <http://www.irishstatutebook.ie>)

Health Service Executive (2010) *National Hospitals Office Code of Practice for Health Records Management: Abbreviations*. Dublin: Health Service Executive (available at <http://www.hse.ie>)

Health Service Executive (2012) *National Service Plan 2012*. Dublin: Health Service Executive. (available at <http://www.hse.ie>)

Health Service Executive (2008) *An Integrated Health System for Ireland*. Dublin: Health Service Executive (available at <http://www.hse.ie>)

Health Service Executive (2006) *Transformation Programme 2007-2010*. Dublin: Health Service Executive (available at <http://www.hse.ie>)

Health Information and Quality Authority (2011) *Report and Recommendations on Patient Referrals from General Practice to Out Patients and Radiology Services Including the National Standard for Patient Referral Information*. Dublin: Health Information and Quality Authority (available at <http://www.hiqa.ie/publications>)

Health Information and Quality Authority (2010) *Guidance on Privacy Impact Assessment in Health and Social Care*. Dublin: Health Information and Quality Authority (available at <http://www.hiqa.ie/publications>)

Health Information and Quality Authority (2010) *Guidance on Developing Key Performance Indicators and Minimum Data Sets to Monitor Healthcare Quality*. Dublin: Health Information and Quality Authority (available at <http://www.hiqa.ie/publications>)

Health Information and Quality Authority (2009) *National Quality Standards: Residential Services for People with a Disabilities*. Dublin: Health Information and Quality Authority (available at <http://www.hiqa.ie/publications>)

Health Information and Quality Authority (2009) *Standards for Residential Care Settings for Older People in Ireland*. Dublin: Health Information and Quality Authority (available at <http://www.hiqa.ie/publications>)

Office of the Nursing and Midwifery Services Director (2011) *Information and Guidance on the Introduction of Nurse and Midwife Medicinal Product Prescribing in General Practice*. Dublin: Health Service Executive (available at <http://www.hse.ie/go/nurseprescribing>)

Office of the Nursing and Midwifery Services Director (2011) *Nurse and Midwife Medicinal Product Prescribing. Application Guidelines for the Education Programmes* 2nd Edition. Dublin: Health Service Executive (available at <http://www.hse.ie/go/nurseprescribing>)

Office of the Nursing and Midwifery Services Director (2011) *Medicinal Product Authorisation. Information and Frequently asked Questions for Registered Nurse Prescribers* Dublin: Health Service Executive (available at <http://www.hse.ie/go/nurseprescribing>)

Office of the Nursing Services Director (2010) *Nurse Prescribing and your child – Information for parents, carers and guardians*. Dublin: Health Service Executive (available at <http://www.hse.ie/go/nurseprescribing>)

Office of the Nursing Services Director (2008) *Guiding Framework for the Implementation of Nurse and Midwife Prescribing in Ireland*. Dublin: Health Service Executive (available at <http://www.hse.ie/go/nurseprescribing>)

Office of the Nursing Services Director (2008) *Nurse and Midwife Prescribers – How they care for you*. Dublin: Health Service Executive (available at <http://www.hse.ie/go/nurseprescribing>)

Scully, G. and Donaldson, L. J. (1998) Clinical governance and the drive for quality improvement in the new NHS in England. *British Medical Journal*. *BMJ* 1998; 317 doi: 10.1136/bmj.317.7150.61 (Published 4 July 1998)
Cite this as: *BMJ* 1998;317:61

State Claims Agency (2010) *Unlicensed and off Licence Use of Licensed Medicinal Products*. Dublin: Clinical Indemnity Scheme (available at <http://www.stateclaims.ie>)

State Claims Agency (2008) *Nurse and Midwife Prescribing*. Dublin: Clinical Indemnity Scheme (available at <http://www.stateclaims.ie>)

European Parliament (2001) DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67) (available at <http://ec.europa.eu>)

Bibliography

- Adams, E., Flynn, M., Cuddy, A., Lorenz, R. and MacGabhann, C. (2010) Nurse and Midwife Medicinal Product Prescribing, A new initiative for Ireland. *Nurse Practitioner Series*. 3 (1): 16-29
- Adams, E., Flynn, M., Cuddy, A., Lorenz, R. and MacGabhann, C. (2010) Nurse and Midwife Medicinal Product Prescribing, The Minimum Dataset. *Journal of Nurse Prescribing*. 8 (5): 234-241
- Adams, J. (2011) Nurse prescribing ethics and medical marketing. *Nursing Standard*. 25 (29): 62-66
- Astles, J. (2006) Extended nurse prescribing: improving care for older people. *British Journal of Nursing*. 15 (3): 150-154
- Banning, M. (2004) Appropriate prescribing for older people: managing the effects of aging. *Nurse Prescribing*. 2 (4): 167-170
- Basford, L. (2003) Maintaining nurse prescribing competence: experiences and challenges. *Nurse Prescribing*. 1 (1): 40-45
- Beckwith, S. and Franklin, P. (2011) *Oxford Handbook of Prescribing for Nurses and Allied Health Professionals* 2nd Edition. Oxford: University Press
- Bradley, E. and Nolan, P. (2007) Impact of nurse prescribing: a qualitative study. *Journal of Advanced Nursing*. 59 (2): 120-128. doi: 10.1111/j.1365-2648.2007.04295.x
- Brooks, N., Otway, C., Rashid, C., Kilty, E. and Maggs, C. (2001) The patient's view: the benefits and limitations of nurse prescribing. *British Journal of Community Nursing*. 6 (7): 342-348
- Callaghan, S. (2011) Nurse prescribing and the PCI specialist nurse role. *British Journal of Cardiac Nursing*. 6 (7): 350-351
- Carey, N. J., Stenner, K.L. and Courtenay, M. (2010). How nurse prescribing is being used in diabetes services: Views of nurses and team members. *Journal of Nursing and Healthcare of Chronic Illness*. 2: 13-21
- Chapman, S. R. (2007) Developing decision support systems for nurse prescribers. *Nurse Prescribing*. 5 (6): 251-255
- Courtney, M. (2008) Nurse prescribing, policy, practice and evidence base. *British Journal of Community Nursing*. 13 (12): 563-566
- Courtney, M. (2000) An overview of the development of nurse prescribing. *British Journal of Community Nursing*. 5 (3): 122-125
- Courtney, M., Carey, N. and Burke, J. (2006) Independent extended and supplementary nurse prescribing practice in the UK: A national questionnaire survey. *International Journal of Nursing Studies*. 44: 1093-1101. Available online at www.sciencedirect.com, doi:10.1016/j.ijnurstu.2006.04.005

- Courtney, M., Carey, N. and Burke, J. (2006) Independent extended supplementary nurse prescribers, their prescribing practice and confidence to educate and assess prescribing students. *Nurse Education Today*. 27: 739-747
- Courtenay, M., Carey, N. and Stenner, K. (2009) Nurse prescriber-patient consultations: A case study in dermatology. *Journal of Advanced Nursing*. 65 (6): 1207-1217 doi. 10/1111/j.1365-2648.2009.04974.x
- Courtenay, M., Stenner, K. and Carey, N. (2009) Nurses' and doctors' views about the prescribing programme. *Nurse Prescribing*. 7 (9): 412-417
- Courtney, M. and Gordon, J. (2009) A survey of therapy areas in which nurses prescribe and CPD needs. *Nurse Prescribing*. 7 (6): 255-262
- Creedon, R. (2010) Nurse prescribing and the need for CPD: an Irish perspective. *Journal of Nurse Prescribing*. 8 (9): 445-448
- Creedon, R. and O'Regan, P. (2010) Palliative care, pain control and nurse prescribing. *Journal Of Nurse Prescribing*. 8 (6): 257-264
- Creedon, R. and O'Connell, L. (2009) Introducing Nurse Prescribing: An Irish Perspective. *Journal Of Nurse Prescribing*. 7 (11): 507-11
- Creedon, R., O'Connell, L., McCarthy, G. and Lehane, B. (2009) An evaluation of nurse prescribing. Part 1: a literature review. *British Journal Of Nursing*. 18 (21): 1322-27
- Davis, D. (2010) Nurse prescribing. *Journal of Community Nursing*. 24 (3): 4-6
- Dhalivaal, J. (2011) Patients perspectives on prescribing by nurses in general practice. *Practice Nursing*. 22 (1): 41-46
- Dobel-Ober, D., Brimblecombe, N. and Bradley, E. (2010) Nurse prescribing in mental health: national survey. *Journal of Psychiatric and Mental Health Nursing*. 17: 487-493
- Drennan, J., Naughton, C., Allen, D., Hyde, A., O'Boyle, K., Felle, P., Treacy, M (P). and Butler, M. (2011) Patients' level of satisfaction and self-reports of intention to comply following consultation with nurses and midwives with prescriptive authority: Across-sectional survey. *International Journal of Nursing Studies*. (2011) doi:10.1016/j.ijnurstu.2011.01.001
- Gleeson, P. (2008) New Horizons for Nurses. *World of Irish Nursing*. 16 (10): 48-49
- Griffith, R. (2006) The role of nurse prescribers in the management of controlled drugs. *Nurse Prescribing*. 4 (4): 155-160
- Hall, J. (2010) Assessing the quality of nurse prescribing. *Nurse Prescribing*. 8 (11): 547-550
- Hannon, V. (2011) The registered nurse prescriber programme is one of the highlights in the history of the HSE so far. *Scope*. 4 (1): 11
- Jutel, A. and Menkes, D. B. (2010) Nurses reported influence on the prescription and use of medication. *International Nursing Review*. 57: 92-97
- Kaasalainen, S., Martin-Misener, R., Carter, N., DiCenso, A. and Donald, F. (2010) The nurse practitioner role in pain management in long-term care. *Journal of Advanced Nursing*. 66 (3): 542-551 doi: 10.1111/j.1365-2648.2009.05206.x
- Keenan, J. (2011) The evolution of nurse prescribing in cardiovascular care. *British Journal of Cardiac Nursing*. 6 (6): 299-302

- Kroezen, M., van Dijk, L., Groenewegen, P. P. and Franche, A.L. (2011) Nurse prescribing of medicines in Western European and Anglo-Saxon countries: a systematic review of the literature. *BMC Health Service Research*. 11 (127). <http://www.biomedcentral.com/1472-6963/11/127>
- Latter, S. (2011) Patient views on nurse prescribing: what does research tell us? *British Journal of Cardiac Nursing*. 6 (7): 346-449
- Lennan, E. and Roe, H. (2010) Nurse prescribing of chemotherapy: docetaxel in early breast cancer. *Nurse Prescribing*. 8 (6): 265-269
- Lockwood, E. and Fealy, G. (2008) Nurse Prescribing as an Aspect of Future Role Expansion: the views of Irish Clinical Nurse Specialists. *Journal of Nursing Management*. 16 (7): 813-20
- McGann, K. (2003) Treating Chronic pain: the nurse's role and the impact of supplementary prescribing. *Nurse Prescribing*. 1 (3): 120-126
- McVeigh, D. M. (2001) Polypharmacy in the Older Population: Recommendations for Improved Clinical Practice. *Topics in Emergency Medicine*. 23 (3): 68-75
- Ndosi, M. and Newell, R. (2010) Medicine information sources used by nurses at the point of care. *Journal of Clinical Nursing*. 19: 2659-2661
- O'Connell, L., Creedon, R., McCarthy, G. and Lehane, B. (2009) An evaluation of nurse prescribing. Part 2: a literature review. *British Journal Of Nursing*. 18 (22): 1398-1402
- Oldknow, H., Bottomley, J., Lawton, M., McNulty, C. and Earle, E. (2010) Independent nurse prescribing for older people's mental health. *Nurse Prescribing*. 8 (2): 66-69
- Parr, C. (2011) A strategy for nurse prescribing. *Nurse Prescribing*. 9 (7): 318-320
- Reddy, B. (2006) Prescribing in older people. *Nurse Prescribing*. 4 (9): 378-381
- Stenner, K., Carey, N. and Courtenay, M. (2010) How nurse prescribing influences the role of nursing. *Nurse Prescribing*. 8 (1):29-34
- Stenner, K., Carey, N. and Courtenay, M. (2010). Implementing nurse prescribing: A case study in diabetes. *Journal of Advanced Nursing*. 66 (3): 522-531 doi. 10.1111/j.1365-2648.2009.05212.x
- Stenner, K., Carey, N. and Courtenay, M. (2010) Nurse prescribing in dermatology: doctors' and non-prescribing nurses' views. *Journal of Advanced Nursing*. 65 (4): 851-859 doi: 10.1111/j.1365-2648.2008.04944.x
- Stenner, K. and Courtenay, M. (2008) The role of inter-professional relationships and support for nurse prescribing in acute and chronic pain. *Journal of Advanced Nursing*. 63 (3): 276-283 doi: 10.1111/j.1365-2648.04707.x
- Stenner, K. and Courtenay, M. (2008). Benefits of nurse prescribing for patients in pain: nurses' view. *Journal of Advanced Nursing*. 63 (1): 27-35 doi:10.1111/j.1365-2648.2008.04644.x
- Stuttle, B. (2010) Non-medical prescribing will remain key in years to come. *Nurse Prescribing*. 8 (11): 515
- Wells, J., Bergin, M., Gooney, M. and Jones, A. (2009) Views on nurse prescribing: a survey of community health nurses in the republic of Ireland. *Journal of Psychiatric and Mental Health Nursing*. 16: 10-17

- White, A. (2002) Practical skills: prescribing consultation in practice. *British Journal of Community Nursing*. 7 (9): 469-473
- Wilhelmsson, S. and Foldevi, M. (2003) Exploring views on Swedish district nurses' prescribing: a focus group study in primary health care. *Journal of Clinical Nursing*. 12: 643-650
- Young, A. (2010) Professionalism and ethical issues in nurse prescribing. *Nurse Prescribing*. 8 (6): 284-290
- Young, D., Jenkins, R. and Mabbett, M. (2009) Nurse prescribing: an interpretive phenomenological analysis. *Primary Health Care*. 19 (7): 32-36

Appendix A: Policy Review Process

The Office of the Nursing and Midwifery Services Director wishes to acknowledge the many services, groups and individuals who contributed to the extensive review of this policy document.

The comprehensive nature of the feedback has informed the further development of this policy document. The time and effort involved is greatly appreciated.

Appendix B: Principles for Clinical Governance Development

To assist health services providers a suite of ten principles for good clinical governance, for the Irish health context, were developed, by an interdisciplinary working group, each with a title and descriptor. Each decision in relation to nurse and midwife medicinal product prescribing (at every level) should be tested against the clinical governance principles set out below:

Principle	Descriptor
Patient First	Based on a partnership of care between patients, families, carers and healthcare providers in achieving safe, easily accessible, timely and high quality service across the continuum of care.
Safety	Identification and control of risks to achieve effective efficient and positive outcomes for patients and staff.
Personal responsibility	Where individuals as members of healthcare teams, patients and members of the population take personal responsibility for their own and others health needs. Where each employee has a current job-description setting out the purpose, responsibilities, accountabilities and standards required in their role.
Defined authority	The scope given to staff at each level of the organisation to carry out their responsibilities. The individual's authority to act, the resources available and the boundaries of the role are confirmed by their direct line manger.
Clear accountability	A system whereby individuals, functions or committees agree accountability to a single individual.
Leadership	Motivating people towards a common goal and driving sustainable change to ensure safe high quality delivery of clinical and social care.
Inter-disciplinary working	Work processes that respect and support the unique contribution of each individual member of a team in the provision of clinical and social care. Inter-disciplinary working focuses on the interdependence between individuals and groups in delivering services. This requires proactive collaboration between all members.
Supporting performance	Managing performance in a supportive way, in a continuous process, taking account of clinical professionalism and autonomy in the organisational setting. Supporting a director/manager in managing the service and employees thereby contributing to the capability and the capacity of the individual and organisation. Measurement of the patients experience being central in performance measurement (as set out in the National Charter, 2010).
Open culture	A culture of trust, openness, respect and caring where achievements are recognised. Open discussion of adverse events are embedded in everyday practice and communicated openly to patients. Staff willingly report adverse events and errors, so there can be a focus on learning, research and improvement, and appropriate action taken where there have been failings in the delivery of care.
Continuous quality improvement	A learning environment and system that seeks to improve the provision of services with an emphasis on maintaining quality in the future not just controlling processes. Once specific expectations and the means to measure them have been established, implementation aims at preventing future failures and involves the setting of goals, education, and the measurement of results so that the improvement is ongoing.

Appendix C: Schedule 8 Drugs

Schedule 8 Drugs which Practitioners who are Registered Nurse Prescribers may prescribe within MDA Schedules 2 and 3

PART 1 - Drugs for pain relief in hospital

I. for the pain relief of a person in a hospital in respect of probable myocardial infarction,
II. for the relief of the acute or severe pain of a person in a hospital after trauma,
or
for the post-operative pain relief of a person in a hospital who has had either condition
described in I or II.

Drug	Route of administration
morphine sulphate	oral, intravenous, intramuscular
codeine phosphate	oral

PART 2 - Drugs for palliative care

Drug	Route of administration
morphine sulphate	oral, subcutaneous
hydromorphone	oral, subcutaneous
oxycodone	oral, subcutaneous
buprenorphine	transdermal
fentanyl	transmucosal, transdermal
methylphenidate	oral
codeine phosphate	oral

PART 3 - Drugs for purposes of midwifery

Drug	Route of administration
pethidine	intramuscular

PART 4 - Drugs for neonatal care in hospital

Drug	Route of administration
morphine sulphate	oral, intravenous
fentanyl	intravenous

Appendix D: State Claims Agency Statement on Nurse and Midwife Prescribing



Clinical Indemnity Scheme



Nurse & Midwife Medicinal Product Prescribing

The Clinical Indemnity Scheme (CIS) was established in July 2002 and is managed by the State Claims Agency. Under the scheme, the State assumes full responsibility for the indemnification and management of all clinical negligence claims against enterprises and practitioners covered by the scheme. This includes the voluntary and statutory services of the Health Service Executive. For more information on which enterprises are covered by the scheme, please go to www.stateclaims.ie.

In relation to nurse and midwife medicinal product prescribing, the CIS provides vicarious indemnity cover to all health practitioners providing professional services for and on behalf of the hospital/enterprise (i.e. Candidate/Registered Nurse/Midwife Prescribers, medical mentors, collaborating medical practitioners, pharmacists).

CIS indemnity is provided in respect of a suit for personal injuries brought by a person alleging negligence, statutory or at common law, in respect of the provision of, or failure to provide, professional medical services. Such a suit may be against any health practitioner, in their role regarding nurse and midwife medicinal product prescribing, whether sued alone or together, arising from the prescribing of a drug or drugs by such a registered nurse/midwife prescriber. The CIS does **not** provide cover in respect of criminal matters i.e. where the Director of Public Prosecutions (DPP) directs criminal charges against a health practitioner.

The CIS does **not** provide representation for health practitioners in relation to fitness to practice issues. In that regard, the State Claims Agency advises health practitioners to purchase additional benefits cover, specifying cover in respect of criminal and fitness to practice matters, from their relevant defence organisations.

For any queries regarding this please contact info@stateclaims.ie

October 2011



Treasury Building, Sráid na Canálach Móire, Baile Átha Cliath 2, Éire
DX: 21 Baile Átha Cliath Gúðán +353 1 664 0900 Facs +353 1 661 8250
Ríomhphost info@stateclaims.ie Suíomh Gréasáin www.stateclaims.ie

Treasury Building, Grand Canal Street, Dublin 2, Ireland
DX: 21 Dublin Telephone +353 1 664 0900 Facsimile +353 1 661 8250
Email info@stateclaims.ie Website www.stateclaims.ie

Appendix E: State Claims Agency Statement on Unauthorised (Exempt) and Authorised Medicines Prescribed for an Unauthorised Indication (Off Label)



Clinical Indemnity Scheme



Use of Unauthorised (Exempt) and Authorised Medicines Prescribed for an Unauthorised Indication Off-Label)

The Clinical Indemnity Scheme (CIS) was established in July 2002 and is managed by the State Claims Agency. Under the scheme, the State assumes full responsibility for the indemnification and management of all clinical negligence claims against enterprises and practitioners covered by the scheme. For more information on which enterprises are covered by the scheme, please go to www.stateclaims.ie.

The Clinical Indemnity Scheme (CIS) provides indemnity to hospitals/enterprises and, vicariously, practitioners in respect of a suit for personal injuries brought by a person alleging negligence, statutory or at common law, in respect of the provision of, or failure to provide, professional medical services.

CIS cover applies equally to the prescription/use of authorised or unauthorised (exempt) medicinal products (including the use of authorised medicinal products prescribed for an authorised indication) providing the latter are used with the express knowledge and consent of the enterprise's management.

It is a policy issue for the hospital/enterprise, and any regulatory body, to decide whether or not to use unauthorised (exempt) medicines and /or authorised medicines prescribed for an unauthorised indication. The CIS does not lay down any guidelines in relation to this

October 2011



Treasury Building, Sráid na Canálach Móire, Baile Átha Cliath 2, Éire
DX: 21 Baile Átha Cliath Gúthán +353 1 664 0900 Facs +353 1 661 8250
Riomphost info@stateclaims.ie Suíomh Gréasáin www.stateclaims.ie

Treasury Building, Grand Canal Street, Dublin 2, Ireland
DX: 21 Dublin Telephone +353 1 664 0900 Facsimile +353 1 661 8250
Email info@stateclaims.ie Website www.stateclaims.ie



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Oifig an Stiúrthóra Náisiúnta Cúnta –
Conarthaí CPPL,
Oifig Náisiúnta na gConarthaí,
Páirc Oifige Bhaile Marlainn,
An Mhuileann gCearr,
Co. na hIarmhí

Office of the Assistant National Director-
PCCC Contracts,
National Contracts Office,
Marlinstown Office Park,
Mullingar,
Co. Westmeath

Teil: Tel: (044) 93 30762
Facs: Fax: (044) 93 30763

Ref: S0222-NCO-09
Date: 27th May 2009

Re: Alignment of Community Drug Schemes to incorporate Nurse and Midwife Prescriptions

Dear Pharmacist,

You will be aware that some nurses and midwives are now authorised to prescribe medicinal products. The Irish Medicines Board (Miscellaneous Provisions) Act 2006 provided for amendment to the definition of practitioner for the purposes of nurse and midwife prescribing. The legislation allows registered nurses or midwives who have: (1) completed an approved education programme; (2) appropriate clinical experience; (3) registered with An Bord Altranais (Irish Nursing Board) as a Registered Nurse Prescriber (RNP); (4) authority from the health service provider who employs them to prescribe a range of medications within their scope of practice.

The introduction of nurse and midwife prescribing does not affect materially the current arrangements for reimbursement under the various Community Drug Schemes. The *Unified Prescription Claim Form* should be completed in the usual manner.

To align the Schemes to incorporate prescriptions generated by RNPs the following arrangements will apply -

- **General Medical Services Scheme (GMS).** The policy decision is that community RNPs will be issued with a pad of standard prescription forms with their own allocated GMS number. This number will be allocated once the Primary Care Reimbursement Service (PCRS) has been notified that the RNP is authorised by the HSE to commence prescribing. These arrangements are under development and a further circular will issue to you, in due course, regarding the details and commencement date.

However an RNP can prescribe for medical card patients under the Hospital Emergency Arrangements and the High Tech Drugs Scheme from the 1st of June 2009.

-
- **Dispensing of Emergency Supplies on a Hospital Prescription Form for a Medical Card (GMS) Patient.** The current arrangements are extended to include a prescription written by a RNP. It is important to be aware that the existing arrangements pertain i.e.

“... for persons who have been in-patients of Acute General Hospitals or who have attended the Accident and Emergency Departments of General Hospitals and when, because of the circumstances of their discharge and/or the urgency of the prescribed medication, it is not possible or very convenient for such persons to attend their general practitioners to have the hospital prescription items transcribed to GMS prescription forms. Out-Patient Department (OPD) prescriptions are not covered by these arrangements.”

You are reminded, “...dispensing of emergency supplies shall be on the day of issue of a hospital prescription – in special circumstances an emergency supply may be dispensed on the following day.”

Please see page 62 of the *Information and Administrative Arrangements for Pharmacists* accessible on the HSE website at:

http://www.hse.ie/eng/PCRS/Contractor_Handbooks/PCRS_Handbook_for_Pharmacists.pdf

- **Supply of High Tech Drugs (HTD).** The current arrangements are extended to include a prescription written by a RNP. The prescription will be written on the *High Technology Medicines Hospital Prescription Form*. The relevant RNP will enter their details in the space allocated for the doctor's details and signature (this form will be amended to incorporate RNPs in the future). RNPs are not authorised to initiate High Tech drug therapies. However, in issuing a maintenance prescription, they are permitted to make dosage changes for therapies already initiated by a consultant.
- **Drugs Payment Scheme (DPS).** The current arrangements are extended to include a prescription written by a RNP. Pharmacists are reminded that the *Protocol for the Supply of Unauthorised Medicinal Products Under the Scheme* will not apply to RNPs, as they are not authorised to prescribe unlicensed medicines.
- **Long Term Illness Scheme (LTI).** The current arrangements are extended to include a prescription written by a RNP. Pharmacists are reminded that *Drugs, Medicines and Non Drug Items reimbursable under the LTI Scheme are intended for the treatment of the primary condition and are approved by the Local Health Office in which the eligible person resides*. As with the DPS, RNPs are not authorised to prescribe unlicensed medicines.
- **Health (Amendment) Act 1996 (HAA).** The current arrangements are extended to include a prescription written by a RNP. As with the DPS, RNPs are not authorised to prescribe unlicensed medicines.

Prescriptions generated by RNPs will be identifiable to you through the inclusion on each prescription of their individual Professional Identification Number (PIN) under which they are registered with An Bord Altranais. The RNP will sign the prescription using his/her *First Name* and *Last Name* along with acronym RNP and the signatory's PIN number. You may confirm that a nurse or midwife is a RNP by checking the nurses register maintained by An Bord Altranais on the “nursingboard.ie” website accessible at www.nursingboard.ie

Your attention is drawn to the particular restrictions on RNPs prescribing controlled drugs (Schedule 2 and 3), details of which are set out in the Misuse of Drugs (Amendment) Regulations 2007 and can be accessed on the Pharmaceutical Society of Ireland Website, at "pharmaceuticalsociety.ie". It should be noted that RNPs are not authorised to prescribe Methadone.

Yours sincerely,

A handwritten signature in black ink, appearing to be 'Pat O'Dowd', written over a horizontal line.

Pat O'Dowd
Asst National Director (Contracts)



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Feidhmeannacht na Seirbhíse Sláinte
Seirbhís Aisioca Príomhchúraim
Bealach amach 5 an M50
An Bóthar Thuaidh
Fionnghlas
Baile Átha Cliath 11

Guthán: (01) 864 7100
Facs: (01) 834 3589

Health Service Executive
Primary Care Reimbursement Service
Exit 5, M50
North Road
Finglas
Dublin 11

Tel: (01) 864 7100
Fax: (01) 834 3589

To

All Registered Nurse Prescribers

Circular No. 013/11

27th July 2011

Re: Community Registered Nurse Prescriber (RNP) Primary Care Prescription Pads

Dear Registered Nurse Prescriber,

The issue of circular SO222-NCO-09 *Alignment of Community Drug Schemes to incorporate Nurse and Midwife Prescriptions* (27 May 2009) stated that the policy decision is that certain HSE community RNPs will be issued with a pad of *Primary Care Prescription Forms* with their own allocated GMS number. This represents the initial phase of developments in the prescription pads used in primary care which ultimately will be used by all prescribers. It encompasses the General Medical Services (GMS), Drugs Payment (DPS), Long Term Illness (LTI) and Health Amendment Act (HAA) prescribing schemes.

This circular sets out the arrangements for certain community RNPs to be issued with Primary Care Prescription Forms. The RNP's GMS number will be allocated once the Primary Care Reimbursement Service (PCRS) has been notified that the RNP is authorised by the HSE employer to commence prescribing.

Community RNPs Employed in Voluntary and Statutory Services of the HSE

Specific criteria will apply to the decision to issue a Community RNP with a Primary Care Prescription Pad confirming that:

- The RNP's service area is a community setting where the RNP is working in collaboration with GPs and GMS prescriptions are normally used.
- The community RNP is a HSE/statutory voluntary sector employee.
- The nurse/midwife applying to use the system is an RNP with current valid registration with An Bord Altranais.
- The RNP's collaborating medical practitioners are currently using the GMS system.
- The Director of Nursing/Midwifery/Public Health or relevant nurse manager has approved the RNP's application to use the GMS prescribing system.
- The HSE Area Manager/Local Health Office (LHO) have supplied notification and authorisation to PCRS for the Community RNP to be issued with a GMS number with a Primary Care Prescription Pad.

RNPs employed in: acute/specialist hospitals; mental health services; private hospitals; private nursing homes and general practice will not be issued with Primary Care Prescription Pads.

Application Process for Primary Care Prescription Pads

A formal application process will be used for each community RNP applying to use the system consisting of a *GMS Form of Notification and Authorisation for RNPs* (see Appendix 1). The form will be initiated by the RNP (Part 1); approved by the Director of Nursing/Midwifery/Public Health/relevant service manager (Part 2); authorised by the HSE Health Area Manager/LHO Manager (Part 3) and PCRS administration (Part 4).

The *Application Form for Notification and Authorisation of the Community RNP* is available through the Office of the Nursing and Midwifery Services Director section of the HSE website at <http://www.hse.ie/go/nurseprescribing>. The completed form should be submitted by the HSE Health Area Manager/LHO Manager to the:

**Data Administration Unit,
Health Service Executive, Primary Care Reimbursement Service,
Units 1-5 Ground Floor,
J5 North Park Offices,
North Park Business Park,
Exit 5 M50,
North Road,
Finglas,
Dublin 11.**

On receipt of your prescription pad from the PCRS please check the accuracy of the preprinted details and keep the pad in a secure place.

Please note the following. The community RNP will:

- Give a commitment to be responsible for the security of the Primary Care Prescription Pad as incorporated in the *GMS Form of Notification and Authorisation for RNPs*.
- Only prescribe medicinal products listed on their Collaborative Practice Agreement (CPA)¹ and also on the List of GMS Reimbursable Items (see details at <http://www.hse.ie/eng/staff/PCRS/items/>).
- Confirm that the person for whom they are prescribing holds valid established eligibility (GMS, DPS, LTI, HAA card). The patient's medical card/eligibility number must be checked carefully before inputting on the prescription.
- Only prescribe those controlled drugs outlined in Schedule 8 of the Misuse of Drugs (Amendment) Regulations 2007 where the medicinal product is listed on their CPA.
- Use non-proprietary (active ingredients) generic names for medicinal products where appropriate when prescribing.
- Not be issued with, or use the three-monthly GMS Repeat Prescription Pad.

The Community RNP will be issued with a Primary Care Prescription Pad in book format with an original and three copies with a facility to record the RNP's Professional Identification Number (PIN):

- Original – for presentation by the patient to the pharmacist
- Copy 1 – for the pharmacist records
- Copy 2 – for the GP records
- Copy 3 – for inclusion in the patients clinical notes maintained by the RNP.

RNPs intending to issue GMS prescriptions must familiarise themselves with the List of GMS Reimbursable Items (see details at <http://www.hse.ie/eng/staff/PCRS/items/>).

¹ Reviewed by the relevant Drugs and Therapeutics Committee, authorised by their Health Service Provider and notified to An Bord Altranais

Completing the Primary Care Prescription

The prescription pad can be used for GMS patients and all other patients covered by the Community Drug Schemes. When completing the prescription please write clearly in block capitals and ensure that your writing is transferred through to each copy. The following should be completed:

- 1 Patient details
 - Enter patients name (as appears on the Medical/Eligibility Card)
 - Enter address
 - Enter health eligibility number and patient code letter (e.g. Medical Card Number/Eligibility Number), for example:
 - Medical Card – 1234567A
 - Drugs Payment Scheme – 1234567B B
 - Long Term Illness – 123456V
 - Health Amendment Act – R12345
 - Enter Personal Public Service (PPS) number where available (this is stated on the Medical Card or Drugs Payment Scheme Card)
- 2 Prescribers details
 - The RNP details including the Prescriber Name, Address and GMS number are pre-printed on the prescription form – confirm the details are correct
 - Enter your prescriber's professional registration number i.e. your An Bord Altranais PIN number
- 3 Prescription details
 - Enter date in numbers in the box provided for example DD/MM/YY
 - Tick the relevant eligibility box (only one should apply)
 - General Medical Services (GMS) i.e. medical card holder
 - Drugs Payment Scheme (DPS) applies to persons who are ordinarily resident in Ireland and do not have a current medical card
 - Long Term Illness (LTI): on approval by the HSE, persons who suffer from one or more of a schedule of illnesses are entitled to obtain, without charge, irrespective of income, necessary drugs/medicines and/or appliances under the LTI scheme, for the primary condition. Where LTI patients hold medical card eligibility their GMS eligibility should be used to access their medications
 - Health (Amendment) Act 1996 (HAA): The Government has provided for the making available without charge of certain health services to certain persons who have contracted Hepatitis C, directly or indirectly, from the use of Human Immunoglobulin Anti-D, or the receipt within the State of another blood product or blood transfusion
 - Unregistered (UR): where the patient does not have valid established eligibility the 'unregistered' box should be ticked
 - Enter the name, formulation, precise strength, dosage and quantity of the medicinal product (Guidance from An Bord Altranais (2010) state that the generic or non-proprietary name of the medication be used on the prescription. However, it is acknowledged that with some medications the proprietary name may need to be used²)
 - Enter age, if under 12 years, in years and months

² An Bord Altranais (2010). *Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority*. Dublin: An Bord Altranais, p 14.

- 4 Complete the prescription
 - Sign the prescription with full signature
 - Give the original and Copy 1 to the patient to bring to the community pharmacist
 - Send Copy 2 to the GP for their records. It is important that the patient's GP is aware of all medicines prescribed for their patients.
 - Include Copy 3 in the patient's clinical notes
- 5 There are a number of fields included in the Primary Care Prescription Pad, with a view to future developments, for example, reference pricing/generic substitution and adherence to guidelines. These fields are not operational at this point in time.

Process for Applying for Subsequent Primary Care Prescription Pads

A reorder form is included in each box of prescription pads. This reorder form should be retained carefully for subsequent use.

Termination or Movement of Employment

All CPAs are considered null and void on the termination/movement of employment for which the CPA was originally intended. Written practice agreements (CPA) should terminate automatically if the RNP or medical practitioner no longer has active, unrestricted registration. If for any reason the RNP's CPA is terminated, all remaining Primary Care Prescription Pads must be returned by the RNP to their Director for return to the office of the Head of Corporate Services, PCRS. They should be accompanied by a letter with notification of termination by the HSE Health Area Manager/LHO Manager.

Practice Nurses employed by GPs

Practice Nurses who are RNPs may be enabled to prescribe under the GMS system. Practice Nurses employed by a GP will not be issued with a separate prescription pad but should be facilitated to use the GMS Prescription Pad that their employer holds within the GP practice setting.

We look forward to working with all our colleagues in this initiative.

Yours faithfully,



Patrick Burke
Assistant National Director
Primary Care Reimbursement Service



Application Form for Notification and Authorisation of Community Registered Nurse Prescriber (RNP)

Introduction

The issue of circular SO222-NCO-09 *Alignment of Community Drug Schemes to incorporate Nurse and Midwife Prescriptions* (27 May 2009) indicated that the policy decision is that HSE community RNPs will be issued with a pad of *Primary Care Prescription Forms* with their own allocated GMS number. This number will be allocated once the Primary Care Reimbursement Service (PCRS) has been notified that the RNP is authorised by the HSE employer to commence prescribing. This form sets out the process for authorisation.

This form is for the use of the Statutory and Voluntary services of the HSE only

Part 1: Registered Nurse Prescriber to complete

I am applying to use the GMS system as a community RNP. Please see below my application details

		Insert Details/Comment							
1	RNP name (use block capitals) ▪ Forename ▪ Surname								
2	An Bord Altranais Personal Identification Number (PIN)								
3	Date registered as an RNP with An Bord Altranais	D	D	M	M	Y	Y	Y	Y
4	HSE Health Area Manager/Local Health Office (LHO) Area of Employment and Health Area /LHO Number								
5	HSE Statutory/Voluntary Services Employee Number (i.e. personnel number)								
6	Contact address of HSE Statutory/Voluntary HSE service where I am employed and from which authorised to prescribe								
7	Contact details ▪ Office telephone (including prefix) ▪ Mobile ▪ email								
8	My clinical area of practice is (for example public health nursing, tissue viability, palliative care etc.)								
9	Name of Collaborating General Practitioner(s) (if multiple please insert names or attach list)								
10	My CPA was authorised (give date)	D	D	M	M	Y	Y	Y	Y
11	I commit to regular audit of my prescribing practice in accordance with An Bord Altranais <i>Practice Standards and Guidance for Nurses and Midwives with Prescriptive Authority</i> (2010) and the <i>Policy for Medicinal Product Prescribing</i> for my service area.	Tick box to confirm				<input type="checkbox"/>			

I am applying to be issued with a GMS number and a supply of Primary Care Prescription Pads and I commit to keeping the prescription pads in a secure place.

Signature of RNP:

Date:

D	D	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---

Part 2: Director of Nursing/Midwifery/Public Health Nursing to complete

Please complete details below for RNP (Insert Yes in each section as applicable)

		Confirmation/Comment
1	I confirm that the nurse/midwife named in Part 1 of this form is a RNP	
2	I confirm that the RNP has a valid CPA and is authorised to prescribe named medicinal products in the service named in Part 1 of this form	
3	I confirm that GMS prescriptions are used in collaboration with GPs for patients attending this service	
4	I confirm that there is a policy and process for maintaining prescription pad security in the service	
5	I confirm that a process is in place for regular audit of the RNPs prescribing practice in accordance with An Bord Altranais Practice Standards and Guidance for Nurses and Midwives with Prescriptive Authority (2010)	

I confirm the details in Part 1 and Part 2 are correct. I approve the RNP's application to use the GMS system in the named clinical area of practice.

Signature of Director:

Date:

D	D	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---

Part 3: HSE Health Area Manager/LHO Manager to complete

I have reviewed the details set out in this Form and authorise the named HSE community RNP to access and prescribe under the General Medical Services Scheme.

Signature of HSE Health Area Manager/LHO Manager:

LHO No:

Date:

D	D	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---

Part 4: PCRS to complete (for internal use)

		Action							
1	HSE Health Area/LHO Number								
2	GMS Number assigned								
3	Date issued	D	D	M	M	Y	Y	Y	Y
4	Details entered	D	D	M	M	Y	Y	Y	Y
5	PCRS Officer								

1 of 4

PRIMARY CARE PRESCRIPTION FORM

[illegible]

PRIMARY CARE PRESCRIPTION PHARMACY COPY

NAME OF PATIENT		OPT OUT OF GENERIC SUBSTITUTION					PHARMACY SEQUENCE NO.	
DATE	ADDRESS OF PATIENT	ITEM NO.	REASON				DISPENSING PHARMACEUTS PROFESSIONAL REG. NO.	
HEALTH ELIGIBILITY NO.		NOT OPERATIONAL					PRESCRIBER'S GMS NO.	
PPS NUMBER							GMS	
							PRESCRIBER'S PROFESSIONAL REG. NO.	

Name, Formulation, Precise Strength, Dosage & Quantity must be stated	Age if under 12 years	Years	Mths	PHARMACIST MUST COMPLETE THIS PART							
				Month Dispensed				Qty. Supplied			
<div style="position: absolute; top: 50%; left: 50%; transform: translate(-50%, -50%) rotate(-30deg); font-size: 4em; opacity: 0.3; pointer-events: none;"> pharmacy Copy SAMPLE </div>											

I CONFIRM THAT THE PRESCRIPTION ABOVE ADHERES TO CURRENT HSE GUIDELINES <input type="checkbox"/>	PHARMACY STAMP AND COMPUTER NUMBER	SERIAL NO.
	PRESCRIBER'S SIGNATURE _____ RECEIVED BY _____ TO BE SIGNED BY PATIENT (OR REPRESENTATIVE)	

PRIMARY CARE PRESCRIPTION GP COPY

[illegible]

PRIMARY CARE PRESCRIPTION RNP COPY

	NAME OF PATIENT						OPT OUT OF GENERIC SUBSTITUTION ITEM NO.					REASON					PHARMACY SEQUENCE NO.				
DATE		ADDRESS OF PATIENT								NOT OPERATIONAL					DISPENSING PHARMACIST'S PROFESSIONAL REG. NO.						
HEALTH ELIGIBILITY NO.															PRESCRIBER'S GMS NO.						
PPS NUMBER															PRESCRIBER'S PROFESSIONAL REG. NO.						
										GMS	DPS	LTI	HAA	UR							
Name, Formulation, Precise Strength, Dosage & Quantity must be stated										Age if under 12 years		Years	Mths	PHARMACIST MUST COMPLETE THIS PART							
<div style="position: relative;"> RNP Copy SAMPLE </div>										Month Dispensed		Drug Code					Qty. Supplied				
I CONFIRM THAT THE PRESCRIPTION ABOVE ADHERES TO CURRENT HSE GUIDELINES <input type="checkbox"/>										PHARMACY STAMP AND COMPUTER NUMBER					SERIAL NO.						
PRESCRIBER'S SIGNATURE _____										RECEIVED BY _____ TO BE SIGNED BY PATIENT (OR REPRESENTATIVE)											



Nurse and Midwife Medicinal Product Prescribing Template

HSE RNP Guidance Process Regarding the Prescribing of Medications for ‘Off Label’ use
Process for the Statutory and Voluntary Services of the Health Service Executive (HSE) to authorise
Registered Nurse Prescribers (RNP) to prescribe an authorised (licensed) medicinal product
in respect of an unauthorised indication (off-label)

Introduction

This document provides a guide for health service providers in reviewing Attachment B of an RNP's Collaborative Practice Agreement (CPA) where the listing contains an authorised (licensed) medicinal product in respect of an unauthorised indication (i.e. off-label).

Background

Arising from the recommendations of the *National Independent Evaluation of the Nurse and Midwife Prescribing Initiative* (Drennan et al 2009) the Department of Health and Children reviewed the relevant medicines legislation and has advised that there is no impediment in the relevant legislation and regulations to prevent a registered nurse from issuing a prescription (in accordance with Reg 5A of the *Medicinal Products (Prescription and control of Supply) Regulations 2003* as amended) for an authorised (licensed) medicinal product in respect of an unauthorised indication (i.e. off-label).

RNPs employed in the statutory and voluntary services of the HSE may be authorised by their employer to prescribe authorised medicinal products for an unauthorised clinical indication (i.e. off-label) once they come within their scope of practice, and the nurse/midwife prescriber is cognisant of best practice in the prescribing of off label medications.

The State Claims Agency has confirmed that the Clinical Indemnity Scheme (CIS) cover applies equally to the prescription/use of licensed or unlicensed medicinal products providing that the latter are used with the express knowledge and consent of the enterprises management (see Appendix 2).

Section 1: To be completed by Candidate/RNP

Please complete all sections and answer the questions below

1	Name of Candidate/RNP <i>Personal Identification Number (PIN)</i>	
2	Clinical area(s) of practice	
3	Name of medicinal product	
4	Dose, route, form	
5	Clinical indication for off-label prescription of the authorised medicinal product	
6	Rationale for inclusion of off label medicinal product on my Collaborative Practice Agreement (CPA) (evidence base must be included/attached)	
7	Is this medicinal product regularly used to treat patients/service users in my area of clinical practice?	
8	Is this medicinal product included in the organisations prescribing guidelines?	
9	Is there an alternative authorised medicinal product that could be prescribed? <i>If the answer is "YES" the Candidate/RNP must not submit this form for authorisation</i>	
10	Is this a new medicinal product? <i>If the answer is "YES" the Candidate/RNP must not submit this form for authorisation</i>	
11	Is this medicinal product on clinical trial? <i>If the answer is "YES" the Candidate/RNP must not submit this form for authorisation</i>	

Signature of Candidate/RNP:

Include Date

Collaborating Medical Practitioners Support

This form should be discussed with the relevant Collaborating Medical Practitioner(s)

I support the inclusion of the above off label medicinal product (ordinarily used in the clinical setting) on the Collaborative Practice Agreement setting out the RNP's scope of practice and prescriptive authority

Signature of Collaborating Medical Practitioner:

Include Date

I support the inclusion of the above off label medicinal product (ordinarily used in the clinical setting) on the Collaborative Practice Agreement setting out the RNP's scope of practice and prescriptive authority

Signature of Collaborating Medical Practitioner:

Include Date

I support the inclusion of the above off label medicinal product (ordinarily used in the clinical setting) on the Collaborative Practice Agreement setting out the RNP's scope of practice and prescriptive authority

Signature of Collaborating Medical Practitioner:

Include Date

Section 2: To be reviewed by the Drugs and Therapeutics Committee

Please complete all sections and answer the questions below

1	Name of medicinal product	
2	The medicinal product is regularly used to treat patients/service users in the Candidate/RNP's clinical area of practice?	
3	The medicinal product is included in the organisations prescribing guidelines?	
4	Is this medicinal product licensed for use in any European Country or other international country? (please specify the country and authorising authority)	
5	There is no alternative authorised medicinal product that could be prescribed?	



Office of the
Nursing & Midwifery
Services Director

6	This is not a new medicinal product?	
7	The medicinal product is not on clinical trial?	
8	Is the committee satisfied with the prescribing information, safety profile and appropriateness of the proposed clinical indications for prescribing the off label medicinal product?	
9	Is there a clear rationale and evidence base for this medicinal product to be prescribed by this RNP?	

The committee has reviewed and considered the information supplied and support the inclusion of the authorised medicinal product in respect of an unauthorised indication (off label) on the RNPs Collaborative Practice Agreement

Signature of Chair of Drugs and Therapeutics Committee:

Include Date

Section 3: Authorisation

This Candidate/RNP is authorised to include this authorised medicinal product in respect of an unauthorised indication (off label) on their Collaborative Practice Agreement and when registered as an RNP is authorised to prescribe the medicinal product within their scope of practice and the organisations prescribing policy.

Name of Medicinal Product

Name of RNP

Clinical Area of Practice

Signature of authorised representative of Health Service Employer:

(Chief Executive Officer/Medical Director/Director of Nursing/Midwifery/Public Health Nursing)

Include Date

This form is available to download from the web site at www.hse.ie/go/nurseprescribing.ie

References

- An Bord Altranais (2010). *Practice Standards and Guidelines for Nurse and Midwives with Prescriptive Authority*. Dublin: An Bord Altranais.
- An Bord Altranais (2007). *Collaborative Practice Agreement (CPA) for Nurses and Midwives with Prescriptive Authority*. Dublin: An Bord Altranais.
- An Bord Altranais (2007). *Guidance to Nurse and Midwives on Medication Management*. Dublin: An Bord Altranais.
- An Bord Altranais (2007). *Decision Making Framework for Nurse and Midwife Prescribing*. Dublin: An Bord Altranais.
- An Bord Altranais (2007). *Requirements and Standards for Education Programmes for Nurses and Midwives with Prescriptive Authority*. Dublin: An Bord Altranais.
- Department of Health and Children (2008) *Building a Culture of Patient Safety: Report of the Commission on Patient Safety and Quality Assurance*. Dublin: The Stationery Office.
- Drinnan J., Naughton, C., Allen, D., Hyde, A., Feele, P., O'Boyle, K., Treacy, P., and Butler, M. (2009). *National Independent Evaluation of the Nurse and Midwife Prescribing Initiative*. Dublin: University College Dublin.
- Irish Medicines (Miscellaneous Provision) Act 2006* (Commencement) Order 2007. Dublin: Stationery Office.
- Irish Medicines Board (Miscellaneous Provision) Act 2006* (No. 3 of 2006). Dublin: Stationery Office.
- Irish Medicines Board (2008). *IMB Guide to the Definition of a Human Medicine*. Dublin: Irish Medicines Board.
- Medicinal Products (Control of Placing on the Market) Regulations 2007-2010*. Dublin: Stationery Office.
- Medicinal Products (Control of Wholesale Distribution) Regulations 2007*, Statutory Instrument No. 538 of 2007. Dublin: Stationery Office.
- Medicinal Products (Control of Manufacture) Regulations 2007*, Statutory Instrument No. 539 of 2007. Dublin: Stationery Office.
- Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007*, Statutory Instrument No. 201 of 2007. Dublin: Stationery Office.
- Medicinal Products (Prescription and Control of Supply) Regulations 2003*. Statutory Instrument No. 540 of 2003 (as amended 2005, 2007 and 2008). Dublin: Stationery Office.
- Misuse of Drugs (Amendment) Regulations 2007*, Statutory Instrument No. 200 of 2007. Dublin: Stationery Office.
- Office of the Nursing and Midwifery Services Director (2011). *Medical Product Authorisation Information and Frequently Asked Questions for Registered Nurse Prescribers*. Dublin: Health Service Executive.
- Office of the Nursing Services Director (2008). *Guiding Framework for the Implementation of Nurse and Midwife Prescribing in Ireland*. Dublin: Office of the Nursing Services Director, Health Service Executive.
- State Claims Agency (2008). *Nurse and Midwife Prescribing*. Dublin: Clinical Indemnity Scheme.
- State Claims Agency (2010). *Unlicensed and off Licence Use of Licensed Medicinal Products*. Dublin: Clinical Indemnity Scheme.