



National Nurse and Midwife Medicinal Product Prescribing Guideline

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Office of the Nursing and Midwifery Services Director,
Health Service Executive

Changing practice to support service delivery

National Nurse and Midwife Medicinal Product Prescribing Guideline

Office of the Nursing and Midwifery Services Director (ONMSD), Health Service Executive (HSE)

This document is a National Guideline

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PART A

Introduction

This national guideline replaces the *National Nurse and Midwife Medicinal Product Prescribing Policy* (Office of the Nursing and Midwifery Services Director (ONMSD), Health Service Executive (HSE), 2018) to reflect legislative and professional regulatory changes. Statutory Instruments (S.I.) No. 529 of 2018 enables the extension of authority to registered nurse/midwife prescribers (RN/MPs) to prescribe exempt medicinal products. The Nursing and Midwifery Board of Ireland (NMBI) have approved the removal of the Collaborative Practice Agreement (CPA) as a regulatory requirement for nurse or midwife prescriber registration and authority to prescribe. This national guideline provides guidance on the development of a clinical governance framework for health service providers.

Health service providers can adopt this national guideline and develop addenda in relation to local governance requirements or develop their own local policies, procedures, protocols and guidelines (PPPG's) incorporating the regulatory requirements and the relevant legislation outlined in page 2-5 of this document. This national guideline provides clear lines of responsibility and accountability to support nurse and midwife medicinal product prescribing which is underpinned by legislation and regulation.

The prescribing of medicinal products is an expanded role that nurses and midwives undertake following successful completion of an approved education programme and having regard to legislation, professional regulation and national and local health service provider PPPG's. Each RN/MP must prescribe within their scope of practice and is individually accountable to keep up-to-date with advances in medicinal product prescribing and clinical practice and must acknowledge any limitations in their competence. Practising in an accountable manner requires a sound knowledge base upon which to make decisions using their professional judgement. The RN/MP must be able to justify and provide a rationale for taking a particular course of action (NMBI, 2019).

The scope and context of practice should be determined with reference to the *Scope of Nursing and Midwifery Practice Framework* (NMBI, 2015) and the *Practice Standards and Guidelines for Prescriptive Authority* (NMBI, 2019) that a RN/MP should adhere to as part of

their professional responsibilities. The relevant medicines legislation, associated regulations, national and health service provider PPPGs must inform prescribing practice of the RN/MP.

There is no legislative requirement for a CPA to be in place before a nurse or midwife can be registered and practice as a prescriber. The NMBI approved the removal of the CPA on 17th April 2018 as a requirement for registration and authority to prescribe for nurses and midwives. The clinical governance for the prescribing of medicinal products is now determined by the local health service provider. For further information please refer to the *Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority, 4rd edn (NMBI, 2019)*.

It is recognised that prescribing practice requires a multidisciplinary approach to the provision of safe patient care and should be planned in a collaborative manner. The sharing of information and advice by multidisciplinary team members is important in promoting evidence-based high quality prescribing, which is a key objective of all prescribers.

Legislation, Associated Regulation and Rules

Primary legislation was introduced in 2006, making provision for prescriptive authority for nurses and midwives subject to conditions specified in subsequent regulations. *The Irish Medicines Board (Miscellaneous Provision) Act 2006* (S.I. No. 3 of 2006) contains an enabling provision for the extension of prescriptive authority for the RN/MP. Following public consultation undertaken by the Department of Health and Children the following were signed into law;

- *Irish Medicines Board (Miscellaneous Provision) Act 2006 (S.I. No. 3 of 2006)*
- *Irish Medicines Board (Miscellaneous Provisions) Act 2006 (Commencement) Order 2007, (S.I. No. 543 of 2007)*
- *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007, (S.I. No. 201 of 2007)*

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

- *Irish Medicines Board (Miscellaneous Provisions) Act 2006 (Commencement) Order (S.I. No. 67 of 2009)*.

Further legislative and regulatory changes were also made to support nurse and midwife medicinal product prescribing;

- *Nurses and Midwives Act 2011 (S.I. No 41 of 2011)*
- *Misuse of Drugs Regulations 2017 (S.I No. 173 of 2017).*
- *Nurses and Midwives Rules 2018 (S.I. No. 219/2018-Register of Nurses and Midwives, S.I. No 218/2018-Education and Training).*
- *Medicinal Products Control of Placing on the Market) Regulations 2018 (S.I. No. 529 of 2018).*

The *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations, 2007* attach the following conditions which must be met where nurse or midwife medicinal product prescribing takes place;

- The nurse or midwife is 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
- NMBI Personal Identification Number (PIN) must be stated on the prescription.

The regulations do not restrict an employer from imposing conditions including prohibiting a RN/MP from prescribing.

The prescribing of controlled drugs is detailed in the *Misuse of Drugs Regulation 2017*, wherein the prescribing of schedule 2 and 3 controlled drugs is restricted to those listed in Schedule 8¹, for the indications and by the route of administration provided for in that Schedule.

The most recent S.I. No. 529 of 2018 provides authority for the RN/MP to prescribe exempt medicinal products within their scope of practice.

¹Drugs which practitioners who are RN/MP may prescribe within Schedules 2 and 3 (*Misuse of Drugs Regulations, 2017*) See Appendix III

Professional Regulations

This national guideline adheres to the regulatory framework for prescriptive authority and has been developed in conjunction with the guidance issued by the NMBI including;

- *Recording Clinical Practice Guidance to Nurses and Midwives (An Bord Altranais², 2002)*
- *Guidance to Nurses and Midwives on Medication Management (An Bord Altranais, 2007).*
- *Requirements and Standards for Education Programmes for Nurses and Midwives with Prescriptive Authority (An Bord Altranais, 2007).*
- *Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives (NMBI, 2014)*
- *Scope of Nursing and Midwifery Practice Framework (NMBI, 2015)*
- *Practice Standards for Midwives (NMBI, 2015)*
- *Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority, 4th edn (NMBI, 2019)*

Scope of Practice

The scope of nursing practice is the range of roles, functions, responsibilities and activities which a registered nurse is educated, competent and has authority to perform. The scope of midwifery practice is the expected range of roles, functions, responsibilities and activities that a midwife registered with the NMBI is educated for and is competent and authorised to perform (NMBI, 2015).

Nursing and Midwifery Board of Ireland Competencies

Competence is understood as the attainment of knowledge, intellectual capacities, practice skills, integrity and professional and ethical values required for safe, accountable and effective practice as a registered nurse or registered midwife (NMBI, 2015).

² The name An Bord Altranais was changed following the signing of *Commencement Order S.I. No. 385 of 2012*, 'the body known as An Bord Altranais, or in the English language as the Nursing Board, established by that section 6 shall continue in being and shall be known as Bord Altranais agus Cnáimhseachais na hÉireann or, in the English language, as the Nursing and Midwifery Board of Ireland' (Government of Ireland, 2012).

The NMBI through its *Requirements and Standards for the Education Programme for Nurses and Midwives with Prescriptive Authority (2007)* and the *Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority (NMBI, 2019)* refers to the RN/MP professional and personal responsibility to maintain individual competency for prescribing practice. There is an obligation for the RN/MP to commit to, and engage in, continuing professional development relating to assurance of competency for her/his prescribing practices.

Upon entry to the division of the Register a nurse or midwife prescriber, it is acknowledged that the applicant has attained the competencies of prescriptive authority through the completion of the education programme. S/he has been deemed competent to prescribe as per the higher education Institution's (HEI's) marks and standards for the theoretical and clinical elements of the programme.

Practice Standards for Registered Nurse and Midwife Prescribers

The professional responsibilities of the RN/MP are addressed in *the Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority (NMBI, 2019)* and should be viewed as the overarching mechanism under which a RN/MP is expected to practice. These specific standards, along with the *NMBI Decision-making Framework for Nurse and Midwife Prescribing and explanatory notes (Appendix I)* outline the requirements of the NMBI for the RN/MP.

The Practice Standards listed in the *Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority (NMBI, 2019)* and the *National Nurse and Midwife Medicinal Product Prescribing Guideline (2020)* supports safe and professional practices for the implementation of nurse and midwife prescribing (NMBI, 2019);

- Practice Standard 1. Clinical decision-making process
- Practice Standard 2. Communication and history-taking
- Practice Standard 3. Documentation
- Practice Standard 4. Prescription writing
- Practice Standard 5. Prescribing for self, family and significant others

- Practice Standard 6. Repeat prescribing
- Practice Standard 7. Prescribing of off-label and exempt medicinal products
- Practice Standard 8. Prescribing by means other than the original prescription
- Practice Standard 9. Separation of responsibilities in the medication management cycle
- Practice Standard 10. Influence of outside interests (relationships with pharmaceutical representation or similar organisations)
- Practice Standard 11. Continuing professional development and continued competency

Each practice standard is described and is accompanied by supporting rationale(s), guidance for practice with reference to *Recording Clinical Practice Guidance to Nurses and Midwives* (NMBI, 2002).

Clinical Governance

Clinical governance is a system through which health service providers are accountable for continually 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. This includes mechanisms for monitoring clinical quality and safety through structured programmes, for example, clinical audit (HIQA, 2019).

Health care providers must have formalised governance structures with clear accountability and responsibility arrangements (HIQA, 2019). It is a framework through which healthcare teams are accountable for the quality, safety and satisfaction of patients in the care they deliver. It is built on the model of the Chief Executive Officer / General Manager or equivalent working in partnership with the Clinical Director, Director of Nursing/Midwifery/ Service Manager/ Designate. A key characteristic of clinical governance is a culture and commitment to agreed service levels and quality of care to be provided (HSE, 2014).

Governance for quality involves having the necessary structures, processes, standards and oversight in place to ensure that safe, person centred and effective services are delivered. Governance also ensures the establishment of learning systems so that all experience within a service is shared and used to improve patient/service user care. Good governance for

quality supports strong relationships between frontline staff, patients and senior leaders within any organisation (HSE, 2016).

Health service providers introducing or where nurse/midwife medicinal product prescribing has been implemented should be cognisant of the *Principles for Clinical Governance Development* (HSE, 2012) (Appendix II). This framework supports health care teams who are accountable for the quality and safety of the care that they deliver.

Prescribing Governance for Registered Nurse and Midwife Prescribers

The NMBI competencies and practice standards for nurses and midwives with prescriptive authority combined with the elements outlined in the Royal Pharmaceutical Society (2016) describes good prescribing governance;

- Prescribe Safely;
 - Prescribes within their scope of practice and recognises the limits of own knowledge and skill
 - Knows about common types and causes of medication errors, adverse reactions and how to prevent, avoid and detect them
 - Refer to World Health Organisation for high risk situations and high risk patients (Medication without Harm Campaign)³
 - Keeps up to date with emerging safety concerns related to medicines and prescribing
 - Reports prescribing errors, near misses and critical incidents, and reviews practice to prevent recurrence

- Prescribe Professionally;
 - Ensures confidence and competence to prescribe are maintained
 - Accepts personal responsibility and accountability for prescribing and understands the legal and ethical implications

³Refer to

<https://www.hse.ie/eng/about/who/qid/nationalsafetyprogrammes/medicationsafety/challenge.html>

- Knows and works within legislative and regulatory frameworks for nurse and midwife medicinal product prescribing
- Improve Prescribing Practice;
 - Reflects on own and others prescribing practice, and acts upon feedback and discussion
 - Understands and uses available toolkits to improve prescribing (e.g. auditing of prescribing practices and peer review feedback)
- Prescribe as part of a team;
 - Acts as part of a multidisciplinary team to ensure continuity of care across care settings
 - Establishes relationships with other professionals based on understanding, trust and respect for each other's roles in relation to prescribing
 - Negotiates the appropriate level of support for the role as a prescriber
 - Provides support and advice to other prescribers or those involved in administration of medicines where appropriate

Policies, Procedures, Protocols and Guidelines (PPPGs)

Ensure that PPPGs are comprehensive, appropriate, robust and up-to-date. Health service providers should continuously review PPPGs to ensure that they are in line with evidence based practice, legislation, regulation and that they continue to meet service user's needs and expectations. Health service providers can adopt this national guideline and develop addenda in relation to local governance requirements or develop their own local PPPG incorporating the regulatory requirements and the relevant legislation outlined in page 2-5 of this document.

In addition, it is recommended that the following points are incorporated in local PPPGs;

- The RN/MP refers to the Health Products Regulatory Authority (HPRA) website to access the Summary of Product Characteristics⁴ (SmPC) for all medicinal products they prescribe

⁴ Please refer to Glossary of Terms relating to SmPC

- The RN/MP can refer and liaise with the National Medicines Information Centre (NMIC) which provides advice on the therapeutic use of medicinal products by way of publications (bulletins and newsletters) to all healthcare professionals and by their clinical enquiry answering service.
- The RN/MP can refer to the British National Formulary for medicinal product information and the local health service provider's formulary where ones exist
- Liaise with members of the multidisciplinary team as appropriate regarding medicinal product prescribing
- Liaise with Director of Nursing/Midwifery/Service Manager/Designate, Practice Development/Prescribing Site Coordinator, regarding support for prescribing within the local health service provider
- Discuss and agree the process for audit of prescribing practice as per the *Practice Standards and Guidelines for Prescriptive Authority* (NMBI, 2019)

Audit

The Commission on Patient Safety and Quality Assurance (2008) identified clinical audit as a key and essential component of clinical governance, stating that it 'constitutes the single most important method which any healthcare organisation can use to understand and assure the quality of the service that it provides' (DoHC, 2008, p. 12). The RN/MP must undertake audit of their prescribing practices to ensure that their practice is safe, appropriate, consistent and effectively monitored (HIQA, 2015) as determined by their local health service provider's audit process for prescribing and medicines management (NMBI, 2019). The audit result must be documented and reported to the person with overall responsibility (NMBI, 2019; HSE, 2019) as determined by their local health service provider. The local health service provider should conduct regular audits and implement recommendations to support medication safety.

A suite of documents to support audit of RN/MP's prescribing practice are available at: <https://healthservice.hse.ie/en/about-us/onmsd/onmsd/specific-programmes/nurse-midwife-medicinal-product-prescribing.html>

Risk Management

Two key elements in good prescribing practice are minimising risk and maximising effectiveness (Naughton et al., 2013). In minimising risk, it is important to note that prescribing is a complex process and may be associated with adverse events and unintended consequences. Therefore, it is important that the RN/MP has a thorough understanding of the medication that is being prescribed, including possible side-effects and the interaction the medication may have with other medications (NMBI, 2019).

1.0 Outline of Guideline Steps

The health service provider must clearly outline the functions of clinical governance and line management for nurse and midwife medicinal product prescribing. Where the RN/MP's direct line manager is not their professional nursing or midwifery support person, the health service provider must clearly identify a senior nurse or midwife, either within or outside the organisation, to whom the RN/MP can refer for professional nursing/midwifery support and guidance.

The following sections outline the essential criteria that need to be in place by the health service provider in order to support nurse and midwife medicinal product prescribing. The combined resources of a number of health service providers may be utilised to achieve the required criteria.

The nurse and midwife medicinal product prescribing initiative must have overarching support and oversight from senior executive managers (e.g. Chief Executive Officer, Chief Officer, and Director of Nursing/Midwifery/Service Manager) for each health service provider.

1.1 Chief Executive Officer/Chief Officer/General Manager or other Senior Manager within the Health Service Provider

The Chief Executive Officer/Chief Officer/General Manager or other senior manager within the health service provider is responsible for;

- Identifying, in partnership with the Clinical Director or relevant Clinical Lead, Director of Nursing/Midwifery/Service Manager/Designate, the strategic direction of nurse/midwife medicinal product prescribing in their health service provider and provide the structures required for safe and appropriate prescribing
- Ensuring the prescriptive authority for nurses and midwives is included within the overall clinical governance structure of the health service providers.

1.2 The Director of Nursing/Midwifery or relevant Nurse/Midwife Manager/Designate (Referred to hereafter as the Director)

The Director is responsible for;

- Ensuring governance arrangements are in place to oversee nurse/midwife medicinal product prescribing
- Planning the strategic direction for nurse/midwife medicinal product prescribing in line with national and local PPPGs
- Overall authority to ensure and support timely registration of the nurse/midwife candidate and to authorise them to commence medicinal product prescribing
- Informing medical practitioners/mentors of their role relating to the nurse/midwife medicinal product prescribing education programme
- Delegating responsibilities as deemed appropriate
- Signing the Site Declaration Form⁵ on behalf of the respective health service provider and in so doing commits to ensuring that the following structures are in place;
 - Safe Management;
 - *The HSE Nurse and Midwife Medicinal Product Prescribing Guideline (2020)* or local PPPG is in place
 - Risk management systems and processes are in place for reporting of adverse event, incidents, near misses and medication errors.
 - Practice and Education Development;
 - Robust and agreed multidisciplinary practice arrangements are in place

⁵ The Site Declaration Form can be accessed via the HEI application process

- Appropriate mentoring arrangements with a named medical practitioner/mentor are in place
 - The name of the nurse/midwife applying for the education programme is on the active register of nurses and midwives maintained by the NMBI.
- Health Service Provider;
 - A named individual is identified with responsibility for the initiative locally and for liaising with the education provider, NMBI and ONMSD prescribing team. This person is known as the Prescribing Site Coordinator (PSC)
 - Access to a computer, email and internet for data input to the *Nurse and Midwife Prescribing Data Collection System*, if in use
 - Sponsorship arrangements at local level, setting out study leave and financial agreement for the candidate nurse/midwife prescriber are in place.
 - Audit and Evaluation;
 - A mechanism to audit nurse and midwife medicinal product prescribing practices is in place.

The Director will also;

- Be proactive in securing necessary resources for safe and effective nurse/midwife medicinal product prescribing
- Ensure that nurses and midwives applying to undertake the medicinal product prescribing education programme are selected according to identified service need
- Support the submission of relevant documentation by the candidate to the NMBI to register as a nurse or midwife prescriber, within one month of confirmation of successfully completing the education programme
- On receipt of confirmation of registration, approve and authorise the nurse or midwife prescriber to commence medicinal product prescribing
- Notify the RN/MP of a commencement date for prescriptive authority within their service area
- Ensure that arrangements are in place to provide access to continuing professional development for all RN/MPs

- Address identified issues or breaches of the RN/MP prescribing practices
- In cases where it is necessary to suspend the RN/MP's prescriptive authority, the director will inform the relevant stakeholders
- Provide reports pertaining to nurse/midwife medicinal product prescribing as required.

1.3 Line Manager of Candidate or Registered Nurse /Midwife Prescriber

The Line Manager is responsible for;

- Consulting with the multidisciplinary team and the director, identifying the service need for nurse/midwife medicinal product prescribing
- Consulting with the director and PSC, identifying nurses/midwives to undertake the education programme and supporting the application process
- Supporting the continuing professional development of the candidate and RN/MP
- Informing the director of any issues associated with the RN/MP's prescribing practices and taking appropriate action
- Supporting audit and responding appropriately to audit reports of the RN/MP's prescribing practices.

1.4 Prescribing Site Coordinator

The PSC is responsible for supporting nurse/midwife medicinal product prescribing as delegated by the Director. This may involve;

- Co-ordinating and supporting nurse/midwife medicinal product prescribing at local health service provider level
- Ensuring compliance with the legislative and NMBI regulatory requirements, the *HSE National Guideline for Nurse and Midwife Medicinal Product Prescribing (2020)* or local PPPGs
- Acting as a central point of contact for the candidate and key stakeholders, in relation to nurse/midwife medicinal product prescribing where necessary
- Supporting audit and responding appropriately to audit reports on the RN/MP's prescribing practices.

1.5 Potential Applicants

Potential applicant must;

- Ensure they are registered on the active register of nurses/midwives maintained by the NMBI
- Seek the approval of the director to apply for the approved education programme
- Identify a medical practitioner/mentor who will support them during the education programme
- Comply with the *HSE Nurse and Midwife Medicinal Product Prescribing Application Guidelines for the Education Programmes (2020)*.

1.6 The Medical Practitioner/Mentor

The medical mentor is a consultant medical practitioner or General Practitioner (GP) who has committed to act as a mentor (to the candidate nurse/midwife prescriber) and provide clinical instruction and supervision within the specific clinical practicum for the duration of the education programme (An Bord Altranais, 2007).

The Medical Practitioner/Mentor is responsible for;

- Confirming their commitment to be a mentor through the inclusion of their signature on the *Site Declaration Form*
- Exploring with the candidate their clinical learning needs and agreeing a programme/contract of learning at the start of the education programme. This is specific for each candidate, reflecting their differing clinical skills and experience
- Providing the candidate with supervision, support, teaching and learning opportunities equivalent to 12 days (96 hours) over the duration of the programme. Aspects of this learning may be delegated to other experienced members of the team or experts in the specialty/area
- Providing learning opportunities and information updates necessary for evidence-based medicinal product prescribing practices
- Meeting formally with the candidate at three and six months to review progress
- Formally assessing the candidate prescriber's progress in the clinical setting using the assessment tool provided by the Higher Education Institution (HEI)

- Completing and 'signing off' the candidate's Competency Booklet/Mentor Declaration at the end of the education programme. The candidate must pass the clinical component in order to successfully complete the education programme.

1.7 Candidate Nurse or Midwife Prescriber

The candidate nurse/midwife prescriber must;

- Comply with sponsorship arrangements at local level, setting out study leave and financial agreement
- Liaise with the PSC on their progress as required
- Successfully complete an approved education programme
- Submit the following to the NMBI to have their name entered in the NMBI's Division of the Register for Nurse/Midwife Prescriber within one month of successful completion of the education programme:
 - the completed signed and stamped *Application Form for Registration in the Registered Nurse or Midwife Prescribers Division of the Register*
 - the relevant registration fee

1.8 Eligibility to Prescribe

The RN/MP must;

- Inform their director when they have received a confirmation letter of registration from the NMBI confirming their name is on the NMBI's Division of the Register for Nurse/Midwife Prescriber maintained by the NMBI

The Director must;

- Inform the RN/MP, in writing, of the commencement date on which they are authorised to commence prescribing (Appendix IV).
- A copy of this letter to commence prescribing along with a copy of the NMBI registration should be maintained in the nurse/midwife prescriber's personnel file.

2.0 Registered Nurse / Midwife Prescriber

The RN/MP must;

- Be accountable and professionally responsible for all aspects of their prescriptive authority
- Prescribe within their scope of practice and competencies
- Practice within a framework of professional accountability and legal boundaries
- Commit to, and undertake, continuing professional development to maintain their competence for prescriptive authority
- Inform their director, their line manager and the PSC of any concerns pertaining to their competence regarding their prescriptive authority
- Participate in audit and other quality assurance processes as per the local health service provider
- Utilise the *Nurse and Midwife Prescribing Data Collection System* if they wish to do so or if required as per local health service provider
- Maintain on-going communication and collaboration with members of the multidisciplinary team in order to enhance therapeutic outcomes for patients/service users
- Act as an informed advisor for other candidates undertaking the nurse/midwife medicinal product prescribing education programme
- Register with the Health Products Regulatory Authority (HPRA) in order to receive medication alerts and bulletins relating to medicinal products⁶
- Discuss with their director and the PSC any situations where these responsibilities cannot, or are not being fulfilled.

The *Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority*, (NMBI, 2019) requires the RN/MP to effectively and efficiently communicate with the patient/service user and to complete an accurate and comprehensive medication history. The RN/MP must consider pre-existing medical conditions which may affect the choice of prescribed medication as per the World Health Organisation Global Campaign (WHO, 2019). The RN/MP should only prescribe if they have appropriately assessed the patient/service user and has a valid clinical relationship with the patient/service user.

⁶ This can be accessed at www.hpra.ie

The RN/MP should communicate clearly with the patient/service user in a language that they understand, including the rationale for the prescription, the name of the medicinal product, the purpose of the medicinal product, the possible side effects and signs and symptoms of potential adverse effects and the actions to take if they occur (NMBI, 2019).

3.0 Prescription Writing

Specific standards for prescription writing must be adhered to as required by legislation, regulation and national guideline/local health service provider PPPGs. This also pertains to the safe keeping and accountability associated with prescription pads.

It is recommended that the generic or non-proprietary name of the medicinal product be used on the prescription. However, it is acknowledged that with some medicinal products, the proprietary name may need to be used (NMBI, 2019).

The RN/MP should;

- Record the strength/dosage/route/frequency of the medicinal product, it is recommended that internationally and nationally accepted abbreviations only be used. If a medicine is used on an 'as required' basis, it is good practice to identify the maximum daily dose in 24 hours of the medicinal product.
- Identify when the medication should be discontinued or, if long-term medication is prescribed, a review date must be indicated
- Ensure that the instructions regarding the medicinal products are understood and agreed by the patient/service-user
- Ensure that the written prescription is legible on all copies
- Ensure that corrections must only be made by re-writing the prescription. Use of correction fluid or deleting with a pen is prohibited.

Medicines regulations and NMBI standards pertaining to prescription writing by the RN/MP include;

- *Medicinal Products (Prescription and Control of Supply) Regulations, 2003 (S.I. No. 540 of 2003)*
- *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations, 2007 (S.I. No. 201 of 2007)*

- *Medicinal Products (Control of Placing on the Market) Regulations 2018 (S.I. No. 529 of 2018)*
- *Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority (4th Edition) (2019).*

In summary, legislations and associated regulations require the prescription to;

- Be legible
- State the full name of the person issuing the prescription and include the NMBI Personal Identification Number (PIN)
- The prescription (including computer-generated prescriptions) must be in indelible ink
- The prescription must be dated and signed by the RN/MP with their usual signature
- The full name and address of the patient/service user must be on the prescription
- If a patient/service user is under the age of 12 years, the date of birth is required
- Prescriptions should be written using only approved abbreviations.

3.1 Prescribing by means other than an original prescription

Regulations 7 (5) (b) of the Medicinal products (Prescription and Control of Supply) Regulations 2003 (as amended) requires that a prescription be an 'original'.

There is provision provided for under Regulation 8 of the aforementioned Regulations for the emergency supply of prescription only medicines, where an original prescription cannot be furnished immediately;

- A prescription other than an original, e.g. faxed, may be used in some circumstances from a prescriber in an emergency supply request. Faxed and photocopied prescriptions and medication charts (or copies thereof) are not legally valid prescriptions. An original prescription must be furnished within 72 hours
- Please refer to *Practice Standards and Guidance for Nurses and Midwives with Prescriptive Authority* (NMBI, 2019) and the following link <https://www.thepsi.ie/gns/inspectionenforcement/inspections/InspectorsAdvice/AdviceEmergencySupply.aspx> (Pharmaceutical Society of Ireland, 2018) for further guidance regarding issuing prescriptions in an emergency.

3.2 Prescription Writing for Controlled Drugs

The *Misuse of Drugs Regulations, 2017* states the particular requirements that must be met for the RN/MP to issue a prescription for Schedule 4 and 5 MDA drugs and a named schedule 2 or 3 MDA drugs (Schedule 8). Schedule 8 provides a detailed listing of the drugs, routes of administration and conditions for which Schedules 2 or 3 MDA drugs can be prescribed by the RN/MP (Appendix III). The RN/MP does not have legal authority to prescribe any other Schedule 2 or 3 MDA drug which is not listed in Schedule 8, nor write for a different route of administration of the named drug, nor prescribe for any condition/situation not named in Schedule 8. The RN/MP must adhere to the *Misuse of Drugs Regulations (2017)* and the *NMBI Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority (NMBI, 2019)* when prescribing MDA drugs.

When prescribing MDA drugs, the RN/MP must ensure the prescription;

- is in ink or otherwise so as to be indelible
- clearly indicates the RN/MP's full name, including the first name
- states the NMBI PIN
- is signed by them with their usual signature
- is dated by them
- specifies the RN/MP's work address and telephone number
- specifies the name, including the first name, and address of the person for whose treatment it is issued
- The prescription must specify in the RN/MP's handwriting;
 - The name of the controlled drug to be prescribed
 - The dose of the controlled drug to be taken by the person for whose treatment the prescription is issued
 - In the case of a prescription for a controlled drug which is a preparation the RN/MP must include;
 - The form and, where appropriate, the strength of the controlled drug to be supplied, and
 - Either the total quantity (in both words and figures) of the preparation or the number (in both words and figures) of dosage units, as appropriate, to be supplied

- o In the case of a prescription for a controlled drug which is not a preparation, the total quantity (in both words and figures) of the controlled drug to be supplied
 - o In the case of a prescription for a total quantity to be dispensed in instalments, the number of instalments and the intervals at which instalments may be dispensed
- As per the *Misuse of Drugs Regulations 2017*, repeat prescriptions for Schedule 8 controlled drugs, are not allowed
- Prescriptions for any Schedule 8 controlled drugs are only valid for 14 days from date of issue indicated on the prescription
- Instalment instructions requirements for Schedule 4 Part 1 drugs are the same as Schedule 8
- As per the *Medicinal Products (Prescription and Control of Supply) Regulations 2003* as amended emergency supplies of Schedule 2, 3 and 4 Part 1 drugs controlled drugs are not allowed
- The specific criteria to be included on a prescription for Schedule 2 and 3 (schedule 8) controlled drugs also applies to controlled drugs in Schedule 4 Part 1 of the *Misuse of Drugs Regulations 2017*, i.e. most benzodiazepines and Z-drugs;
 - o the name of the drug
 - o dose
 - o pharmaceutical form
 - o strength (where appropriate)
 - o the total quantity of the controlled drug to be dispensed **written in both words and figures**
- Controlled drugs in Schedule 4 Part 1 are not required to be handwritten.

3.3 Repeat Prescription versus Instalment

The RN/MP should be knowledgeable of the medicinal product regulations relating to the supply/dispensing of medicinal products in instalments for the duration of individual prescriptions. Repeat prescribing may arise in situations where the original issued prescription was issued and the patient/service user requests or requires a continued course of medication. A “repeat prescription”, as defined in the Medicinal Products (Prescription

and Control of Supply) Regulations 2003, as amended, means a prescription which may be dispensed more than once.

- Schedule 2 and Schedule 3 (Schedule 8) controlled drugs cannot be repeated
- Schedule 4 (part 1 and part 2) and schedule 5 controlled drugs may be repeated

“Instalments” allow the total quantity of the medicine prescribed to be dispensed in smaller, specified amounts, at specified intervals.

All controlled drugs can be legally dispensed in this manner, however, in accordance with the Misuse of Drugs Regulations 2017, ‘the number of instalments and the intervals at which the instalments may be dispensed’ must be specified on prescriptions for schedule 2, schedule 3 and schedule 4 part 1 prescriptions.

4.0 Prescribing for Off-Label Use and Exempt Medicinal Products

The Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority (NMBI, 2019), Practice Standard 7, provide guidance on off-label and exempt medicinal product prescribing by the RN/MP. The candidate/RN/MP should also refer to the document *Nurse Midwife Medicinal Product Prescribing Authorised, Off-label and Exempt Medicinal Products Information Sheet (HPRA and HSE, 2020)*⁷ for further information regarding the prescribing of medicinal products for off-label use and exempt medicinal products.

4.1 Off-label Medicinal Product

Off-label use refers to the use of an authorised medicinal product outside the terms of its marketing authorisation (MA) or product registration. It is the prescribing of the medicinal product that is off- label, rather than the medicinal product itself (HSE & HPRA, 2020). The *Medicinal Products (Control of Placing on the Market) Regulations 2007* as amended do not prohibit the sale, supply, manufacture, possession or procuring the sale, supply, manufacture of a medicinal product for off-label use. It is permissible for an authorised or registered medication to be supplied from a prescription issued by any prescriber, including where it has been prescribed for off-label use.

⁷ This can be accessed from <https://healthservice.hse.ie/en/about-us/onmsd/onmsd/specific-programmes/nurse-midwife-medicinal-product-prescribing.html>

The issuing of a prescription for an off-label indication must be in accordance with Regulation 5A of the *Medicinal Products (Prescription and Control of Supply) Regulations 2003* (SI 540/2003) as amended. There is no impediment in the relevant legislation or professional regulation to a RN/MP prescribing a medicinal product for off-label use.

4.2 Exempt Medicinal Product

An exempt medicinal product (EMP) is a medicinal product that is not authorised or registered in Ireland either by the HPRA or in the case of a centrally authorised medicinal product, by the European Commission (via the European Medicines Agency), but which can be legally supplied in response to a *bona fide* unsolicited order, formulated in accordance with the specifications of a registered medical practitioner or registered dentist for use by their individual patients on her/his direct personal responsibility, in order to fulfil the special needs of those patients (Ref. *Medicinal Products (Control of Placing on the Market) Regulations, 2007, as amended.*) This legislation provides statutory authority for a medical practitioner to treat a patient under her/his care, using exempt medicinal products.

The enactment of S.I. No. 529 of 2018 provides the authority for the prescribing of exempt medicinal products by RN/MPs. This action is within the nurse or midwives scope of practice for prescriptive authority, supports evidence based practice and provides for an unmet clinical need.

4.3 Guidance for Practice

In tandem with the legislative requirements RN/MPs should be aware of best practice guidance and health service provider's PPPGs when prescribing for off-label use or EMPs. As with all decisions in prescribing medicinal products, the prescribing for off-label use and EMPs must be within the RN/MP's scope of practice.

The RN/MP must be knowledgeable of best practice for prescribing medicinal products for off-label use and EMPs.

This includes determining:

- if there is an alternative authorised or registered medicinal product that could be prescribed
- if the medicinal product is regularly used to treat patient/service users in the RN/MP's area of clinical practice

The health service provider's PPPGs for nurse and midwife medicinal product prescribing should outline the governance structures for RN/MPs to prescribe all medicinal products. This ensures the safety and quality of care for patients and service users.

5.0 Security and Safe Handling of Prescription Pads

Prescription pads are the property of the respective employing health service provider and should be stored securely. The RN/MP should;

- Ensure that prescription pads are stored in a secure place under lock and key when not in use
- 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, Primary Care Reimbursement Services (PCRS) and complete and submit the relevant incident management form as per health service provider PPPGs
- Report loss to the director, or designated person, and on behalf of the health service provider, they should report any such incident to An Garda Síochána
- Report the loss, and verify (where possible) the serial number and identify the number of unused prescription sheets remaining in the prescription pad

6.0 Adverse Reactions and Medication Errors/Near Misses

6.1 Adverse Reactions

The RN/MP should keep up to date with all prescribing information of the medicinal products they prescribe including up-to-date safety information. The management of an adverse drug reaction (ADR) depends on the type of ADR. Clinical judgement, assessing the

benefit-risk of the medicine (with the help of investigations) and the severity of the reaction, is required to determine whether a drug needs to be stopped (consider alternative treatments that could be used instead) or the dose regimen adjusted. In addition, it may not always be appropriate either to abruptly cease treatment, as tapering of treatment may be required. There are a number of factors to consider in deciding if appropriate to discontinue a medicine and the following steps should be taken;

- The RN/MP or nurse/midwife should remain with the patient/service user and closely monitor the ADR
- The patient/service user (and/or family/carer where appropriate) should be informed of what has happened by the RN/MP or relevant nursing/midwifery and/or medical staff as per the *National HSE Open Disclosure Policy (HSE, 2019)*
- Vital signs should be recorded in line with local health service provider PPPGs
- The relevant medical practitioner should be informed immediately and the patient/service user should be reviewed by a medical practitioner
- The adverse reaction and all relevant nursing/midwifery and medical management and interventions must be recorded promptly
- Where available, all vials, ampoules, infusions and remaining batches of medicinal preparations should be retained in accordance with local PPPGs
- The RN/MP or relevant nursing/midwifery staff must report any suspected adverse reactions to relevant staff i.e. the pharmacy department/dispensing pharmacist/clinical risk manager in line with local PPPGs
- On discharge the patient's GP should be informed as appropriate
- The RN/MP or relevant nursing/midwifery staff must report to the HPRA any suspected adverse reactions, in accordance with criteria outlined by the HPRA. This reporting may be carried out on line at <http://www.hpra.ie> ("Report an Issue" tab) or through use of the downloadable or post-paid yellow card options. Downloadable forms may be completed manually and submitted to the HPRA via "freepost". Yellow cards are available on request from the HPRA at **01 6764971**
- The RN/MP or relevant nursing or midwifery staff may advise patients/service users that they can submit a report to the HPRA on any adverse reactions that may occur

- The incident and all actions taken must be promptly recorded and the relevant incident management form completed and submitted as per health service provider's PPPGs.

6.2 Medication Errors/Near Misses

When an incident occurs/is identified, the first response must be to the person directly affected. It is important to focus first and foremost on the affected person's physical needs through the provision of appropriate medical treatment or other care to manage the harm that has occurred, relieve suffering and minimise the potential for further harm to occur.

All incidents involving patients/service users should be factually documented in the patient/service user's clinical/care record, including details of the care provided and in accordance with the National *HSE Open Disclosure Policy*, 2019.

When any immediate action has been taken, the staff identifying the incident should, if they have not already done so, notify the incident to the manager on duty within the area where the incident occurred.

In the case of medication errors or near misses that may directly involve the patient/service user, i.e. wrong medication/dose/route being prescribed or administered, or another prescribing error, the RN/MP or nursing/midwifery staff must remain with the patient/service user and closely monitor them for any adverse reactions.

- Vital signs should be recorded and the patient/service user should be reviewed as soon as possible by the medical practitioner
- The incident must be reported to the line manager as soon as possible
- If further advice/information is required, contact the National Medicines Information Centre at St. James's Hospital at **+353 (0) 1 473 0589/1850 727727**, or the National Poisons Information Centre in Beaumont Hospital at **+353 (0)1 809 2566/+353 (0)1 837 9964**
- The incident and all actions taken must be promptly recorded and the relevant incident management form completed and submitted as per health service provider's PPPGs

- The patient/service user (and family or carer where appropriate) must be informed of the incident as per National *HSE Open Disclosure Policy* (HSE, 2019)
- Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined in section 6.1.

It is also the responsibility of the staff to complete the appropriate National Incident Report Form (NIRF 01 – V10) as per the Incident Management Framework (HSE, 2018) available at: <https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v10-person1.pdf> as soon as is feasible after the event occurs and within one working day. In completing a NIRF, staff must ensure that they provide all information and complete all mandatory fields required by the NIRF and ensure that any information provided is factual and not subjective. Health service providers must clearly identify the route for submission of the NIRF for input onto the National Incident Management System (NIMS). The entering of an incident onto NIMS fulfills the health service provider’s obligation to inform the State Claims Agency.

7.0 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 V, VI). This includes the statutory and voluntary services of the HSE.

- The RN/MPs are individually and professionally accountable to the NMBI and their health service provider for all decisions pertaining to their medicinal product prescribing practice
- The State Claims Agency has issued a statement in relation to clinical indemnity in respect of nurse and midwife medicinal product prescribing in the voluntary and statutory services of the HSE .Details of cover provided for all clinical practitioners are outlined in Appendix V, VI.
- The State Claims Agency has issued a statement in respect of clinical indemnity in relation to exempt medicinal products and medical products prescribed for off-label use (Appendix VI)

- Private practice settings (GPs, private nursing homes, private hospitals) or their indemnity/insurance providers are not required to extend indemnity cover to HSE employees authorised to practice in their service. The HSE RN/MP practising in a private setting remains indemnified at all times by the Clinical Indemnity Scheme for the provision of services
- General Practitioners providing a service to HSE statutory and voluntary services for example, community nursing units, community and/or district hospitals are indemnified by the Clinical Indemnity Scheme, State Claims Agency.

8.0 Community Drug Prescribing

8.1 Community Drug Prescribing Schemes

The issue of Circular SO222-NCO-09 by the Primary Care Reimbursement Service (PCRS) stated 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 encompasses the following schemes:

- General Medical Services Scheme (GMS)
- Drugs Payment Scheme (DPS)
- Long Term Illness Scheme (LTI)
- Health (Amendment) Act (HAA)

8.2 Primary Care Prescription Form

Circular number 013/11 sets out the arrangements for certain community RN/MP to be issued with Primary Care Prescription Forms. The RN/MP’s GMS number will be allocated once the PCRS has been notified that the RN/MP is authorised by the health service provider to commence prescribing.

- Specific criteria will apply to the decision to issue certain community RN/MPs with a Primary Care Prescription Pad

- In order to be issued with a Primary Care Prescription Pad, the RN/MP must complete *The Application Form Notification and Authorisation of the Community Registered Nurse/Midwife Prescriber*. (Appendix VII).

PART B

1.0 Initiation

Prescriptive authority for nurses and midwives is founded on a dual framework of medicines legislation, associated regulation and professional regulation. This national guideline has been developed in partnership with key stakeholders to comply with the HSE statutory obligations and to give practical effect to the governing legislation, regulation and NMBI guidance documents.

1.1 Purpose

This national guideline was originally developed as a policy and has been revised to provide information and guidance to support health service providers with the introduction and implementation of nurse/midwife medicinal product prescribing in the statutory and voluntary services of the HSE.

1.2 Scope

This national guideline applies to;

- RN/MPs employed in the HSE, who have received a commencement date from the director to commence prescribing in a named area of practice and whose name is entered on the NMBI's Division of the Register for nurse/midwife prescribers maintained by the NMBI
- Nurses and midwives employed in statutory and voluntary services of the HSE who are undertaking, or have undertaken an approved education programme in Nurse/Midwife Medicinal Product Prescribing, and/or are in the process of registering as a RN/MP with the NMBI
- All key stakeholders supporting nurse/midwife medicinal product prescribing in the in the statutory and voluntary services of the HSE.

1.3 Aim and Objectives

1.3.1 Aim

The aim of this national guideline is to provide guidance for the development of a clinical governance framework for health service providers, outlining clear lines of responsibility and accountability to support nurse/midwife medicinal product prescribing, which is underpinned by legislation and regulation.

1.3.2 Objectives

- Support best practice with regard to nurse and midwife medicinal product prescribing
- Support the safety of patients/service users and staff
- Support health service providers where nurse and midwife medicinal product prescribing has or is being implemented.
- Link nurse and midwife medicinal product prescribing to strategic service planning

1.4 Outcomes

This national guideline will provide information and guidance to promote and enhance evidence based practice in nurse and midwife medicinal product prescribing in Ireland.

1.5 Guideline Review Group

The National Nurse and Midwife Medicinal Product Prescribing Team, ONMSD HSE. (Appendix VIII).

1.5.1 Conflict of Interest

Conflict of Interest Forms were completed by the Guideline Review Group and no conflicts of interest were noted (Appendix IX).

1.5.2 Funding Body and Statement of Influence

This national guideline was commissioned by the HSE. The national guideline content was not influenced by the HSE or any other funding body. This process was fully independent of lobbying powers. The guideline content is based on current best research evidence, legislation, associated regulation, professional regulation and relevant expertise.

1.6 Guideline Governance Group

The Director of the Office of Nursing and Midwifery Services (ONMSD, HSE) and the Chief Clinical Officer (CCO, HSE) commissioned this national guideline. The National Lead for nurse and midwife medicinal product prescribing (who reports to the ONMSD), managed, coordinated and administered the process.

1.6.1 Membership of the Approval Governance Group.

Refer to Appendix X for membership of the Approval Governance Group.

1.7 Supporting Evidence

References can be found in Section 8.0. Other supporting evidence can be found within the appendices.

1.7.1 Legislation, Regulation and Other Related Policies

Refer to Part A.

1.7.2 Policy Being Replaced by this Guideline

National Policy for Nurse and Midwife Medicinal Product Prescribing (HSE, 2018).

1.8 Glossary

See Appendix XI for a full glossary.

2.0 Guideline Development

2.1 Guideline Methodology

The evidence relating to nurse and midwife medicinal product prescribing was collected, critically appraised and used in this national guideline to update the exiting *National Policy for Nurse and Midwife Medicinal Product Prescribing* (HSE, 2018).

2.2 Literature Search Strategy

A comprehensive literature search was undertaken in 2017 which included a national and international literature review and peer review journals. The Guideline Review Group focused on updated Irish legislation and associated regulations, professional regulation and relevant publications to inform this national guideline. Articles from 2018 – 2019 were prioritised, the timeframe since the previous policy (HSE, 2018).

2.3 Evidence Appraisal

Evidence appraisal was not applicable for this national guideline.

2.4 Grading of Recommendations

Grading of recommendations was not applicable for this national guideline.

2.5 Summary of the Evidence

The model adopted in Ireland for Nurse and Midwife Medicinal Product Prescribing was independent and collaborative, as identified and demonstrated in the *Report on Nurse and Midwife Medicinal Product Prescribing Review of Systems and Processes* (HSE, NMBI, 2015).

A review of the literature demonstrated that nurse and midwife medicinal product prescribing has given rise to many benefits, from the perspective of the service user, nurse /midwife prescriber and the organisation (Graham-Clarke et al, 2019; Courtenay, 2019; Oxtoby, 2016; McBrien, 2015; Stenner et al, 2010). These include;

- Speed of access to care, consultation and advice on treatment and medications

- Time saving and convenience
- Increased compliance
- Patients' confidence in the knowledge and skills of the nurse or midwife
- Job satisfaction
- Autonomy, responsibility and credibility
- Enhanced delivery of holistic care
- Better use of nursing skills
- More flexible team working
- Reduced drug wastage.

Inter-professional relationships, team working, peer support, clinical supervision and continuing professional development (CPD) have been identified as factors necessary to facilitate prescribing (Courtenay, 2013). These factors are in place in Ireland through the interdisciplinary approach, and through the provision of regular CPD days for RN/MPs, master classes on medication management and a national conference with international speakers on nurse and midwife medicinal product prescribing hosted on alternate years. These factors also support other members of the multidisciplinary team.

Adopting a national, standardised approach in Ireland has provided clarity on nurse and midwife medicinal product prescribing across the health service as demonstrated in the HSE and NMBI review undertaken in 2015. Research shows that non-medical prescribers were as effective as medical prescribers in achieving medication adherence, patient satisfaction and positive outcomes across a range of conditions (Weeks et al, 2016). A report by the *UK Health Education North West* (2015) evaluated the economic impact of non-medical prescribing. While this was a UK study, the findings can be applied to the Irish context. The study reported the following benefits:

- Non-medical prescribers reported that 33% of their consultations prevented a GP appointment
- Some consultations prevented a hospital admission
- Non-medical prescribing has the potential to save £777 million annually in England

- Non-medical prescribers make a significant contribution to the National Health Service (NHS) under the broad headings of improved patient care and return on investment
- Policy makers at UK Government, and NHS England levels should be ‘particularly interested in the economies non-medical prescribing practitioners can contribute’
- Strategic use of non-medical prescribers in primary and secondary care settings can be an important response to the continuing tightening of financial support at a time of greater demand
- Primary care involvement means that A&E attendance, non-elective admissions and readmissions can be reduced. Once patients are admitted, they can benefit from faster, safer care and discharge than might not otherwise be the case.

A joint review by the HSE and NMBI (2015) identify national and international trends that support the continued advancement of nurse and midwife prescribing including:

- Social and demographic change
- Changing health service provision and reconfiguration
- Increased specialisation of services
- Value for money including a return on investment in the education of health care professionals
- Implementation of the European Working Time Directive
- Greater focus on community based services.

In Ireland, nursing and midwifery policy direction supports the above findings. The Department of Health (DoH) *Statement of Strategy (2016-2019)* outlines nurse and midwife medicinal product prescribing as a national, measurable priority. This strategy outlines five strategic priorities. Priority 3 is to ‘create a more responsive, integrated and person-centred health and social care service’ (p.6).

A Policy on the *Development of Graduate to Advanced Nursing and Midwifery Practice (DoH, 2019)* outlines the future direction for role expansion in a structured way to address emerging and future service needs and drive integration between services. It identifies nurse and midwife prescribing as integral and a critical component for service delivery. The *HSE*

National Service Plan (2020) supports the expansion and development of nursing and midwifery roles from graduate to advanced practice through education, site development and monitoring of clinical nurse/midwife specialists and advanced nursing/midwifery practitioners.

The HSE National Service Plans 2017 and 2018 identified increasing capacity of RN/MPs as a priority within the nursing/midwifery services (HSE, 2017, 2018). One of the key objectives of the *HSE National Service Plan (2019)* was to strengthen the capacity and capability within nursing and midwifery to enhance frontline clinical leadership and practice. *The Sláintecare Report (2017)* endorsed a number of health reforms to provide timely access to safe and high quality care, on the basis of medical need which is integrated with community care services, working together and practising outreach and in-reach, where appropriate. Nurse and midwife medicinal product prescribing supports Goal 2 *Sláintecare Implementation Strategy (2019)* which is to 'provide high quality, accessible and safe care that meets the needs of the population' (p.6).

The benefits of nurse and midwife medicinal product prescribing have been consistently reported in the literature and the evidence suggests that as nurses and midwives take on new roles and responsibilities the authority and ability to prescribe has improved both accesses to medicines and the timeliness of interventions for those seeking treatment.

2.6 Resources

A budget impact analysis was not undertaken. This national guideline is a revision of the National Policy for Nurse and Midwife Medicinal Product Prescribing published in 2018. The guideline reflects current evidence based practice and should be budget neutral for its on-going implementation at health service provider level.

2.7 Outline of the Guideline Steps

Refer to Part A for the details of this national guideline.

3.0 Governance and Approval

3.1 Governance

The sponsors of this guideline development, the Director of the ONMSD and the Chief Clinical Office, Health Service Executive, have the authority and responsibility for managing and executing this national guideline. The Guideline Review Group worked within available resources to develop this national guideline.

3.2 Method for Assessing this Guideline as per the HSE National Framework for Developing Policies, Procedures, Protocols and Guidelines (PPPGs)

This national guideline was reviewed to ensure compliance with *The Policies, Procedures, Protocols and Guidelines Checklist for Developing Clinical PPPGs (HSE, 2016)* (Appendix XII).

3.2.1 National Stakeholder and Expert Review

Once this draft guideline received approval from the Guideline Review Group, consultation process was undertaken with relevant internal and external stakeholders.

3.3 Copyright/Permission Sought

No copyright or permissions were required for this national guideline.

3.4 Approval and Sign Off

The final draft of the *HSE National Guideline for Nurse and Midwife Medicinal Product Prescribing (2020)* was submitted for approval, accompanied by the signed *PPPG Checklist* (Appendix XII) confirming that all stages of this national guideline had been completed in accordance with the *HSE National Framework for Developing Policies, Procedures, Protocols and Guidelines (PPPGs)* (HSE, 2016). It was then signed off by the director of the ONMSD and the CCO HSE.

4.0 Communication and Dissemination

Once this national guideline is approved and signed off nationally it should be disseminated as soon as possible to all local health service providers and relevant stakeholders. This approach will ensure that the guidance and information in this national guideline can be used to support candidates, RN/MPs and health service providers involved in nurse and midwife medicinal product prescribing.

The following activities will be undertaken;

- All relevant stakeholders to receive an electronic copy of the national guideline
- Upload the national guideline to relevant webpage:
<https://healthservice.hse.ie/en/about-us/onmsd/onmsd/specific-programmes/nurse-midwife-medicinal-product-prescribing.html>
- Liaise with PSCs in all health service providers for on-going dissemination
- Disseminate through the ONMSD HSE communication channels
- Circulate via the RN/MP and PSC eNetworks.

5.0 Implementation

5.1 Implementation of the Guideline

It is the responsibility of the local health service provider to adopt this national guideline and develop addenda in relation to local governance or develop their local PPPG to support the implementation of nurse and midwife medicinal product prescribing.

The ONMSD is responsible for leading the national implementation of nurse and midwife medicinal product prescribing in Ireland and have provided a suite of documents to support the initiative that is available at the following link:

<https://healthservice.hse.ie/en/about-us/onmsd/onmsd/specific-programmes/nurse-midwife-medicinal-product-prescribing.html>

5.2 Barriers and Facilitators to Implementation

There are no known barriers that will impact the implementation of this national guideline.

5.3 Education

Education sessions will be provided on this national guideline if required.

5.4 Responsibility for Implementation

All health service providers involved in nurse and midwife medicinal product prescribing have a responsibility for the implementation of this national guideline or their own local PPPG. Refer to Part A for detailed responsibilities for individual stakeholders.

5.5 Health Service Provider Responsibility

Each Chief Executive Officer, Chief Officer, General Manager, Director and the Clinical Director of the health service provider have corporate responsibility for the implementation of this national guideline or their own local PPPG.

5.6 Roles and Responsibilities

Senior Manager;

- Support the implementation of this national guideline or local PPPG
- Assign personnel with responsibility, accountability and autonomy to implement this national guideline or local PPPG
- Provide managers with support to implement this national guideline or local PPPG
- Ensure clinical and educational staff are supported to implement this national guideline or their own local PPPG
- Monitor the implementation of this national guideline or their own local PPPG
- Ensure audit processes for prescribing practices are in place.

Head of Department;

- Ensure all relevant staff members are aware of this national guideline or local PPPGs and are supported to undertake education programmes and related training, as appropriate.

Clinical Staff;

- Clinical staff should comply with this national guideline or their own local PPPG. A copy of the signature sheet should be signed to show all relevant staff have read, understand and agree to adhere to this national guideline or local PPPG (Appendix XIII).

6.0 Monitoring, Audit and Evaluation

6.1 The Plan

It is anticipated that this national guideline will provide national guidance and information on the introduction and implementation of nurse and midwife medicinal product prescribing. It is important that this national guideline or local PPPG is audited to support continuous quality improvement in relation to its implementation. The audit process should be undertaken from a multidisciplinary perspective.

6.1.1 Monitoring

The Chief Executive Officer, Chief Officer, General Manager, Clinical Director and Director in each local health service provider have responsibility for supporting the implementation and monitoring of this national guideline or their local PPPG.

6.1.2 Audit

Audit of this national guideline or local PPPG should be undertaken to provide evidence to support continuous quality improvement.

6.1.3 Evaluation

Evaluation of the effectiveness of this national guideline or local PPPG should be undertaken locally to support its implementation and sustainability.

7.0 Revision/Update

7.1 Procedure for Revising the Guideline

The Guideline Review Group has agreed that this national guideline will be reviewed on a 3-yearly basis and updated as appropriate. Therefore, this national guideline will be reviewed in 2023. An updated literature search will be undertaken at that time and the national guideline amended as appropriate.

7.2 New Evidence

As evidence emerges that require changes in practice a further review of the literature will be undertaken so that the national guideline will maintain its relevance and currency

7.3 Version Control

The original *National Policy for Nurse and Midwife Medicinal Product Prescribing* was issued in 2012. This national guideline replaces the *National HSE Policy for Nurse and Midwife Medicinal Product Prescribing* (2018). This national guideline will be available on the HSE website. This is a controlled national guideline and will be available electronically at:

<https://healthservice.hse.ie/en/about-us/onmsd/onmsd/specific-programmes/nurse-midwife-medicinal-product-prescribing.html>

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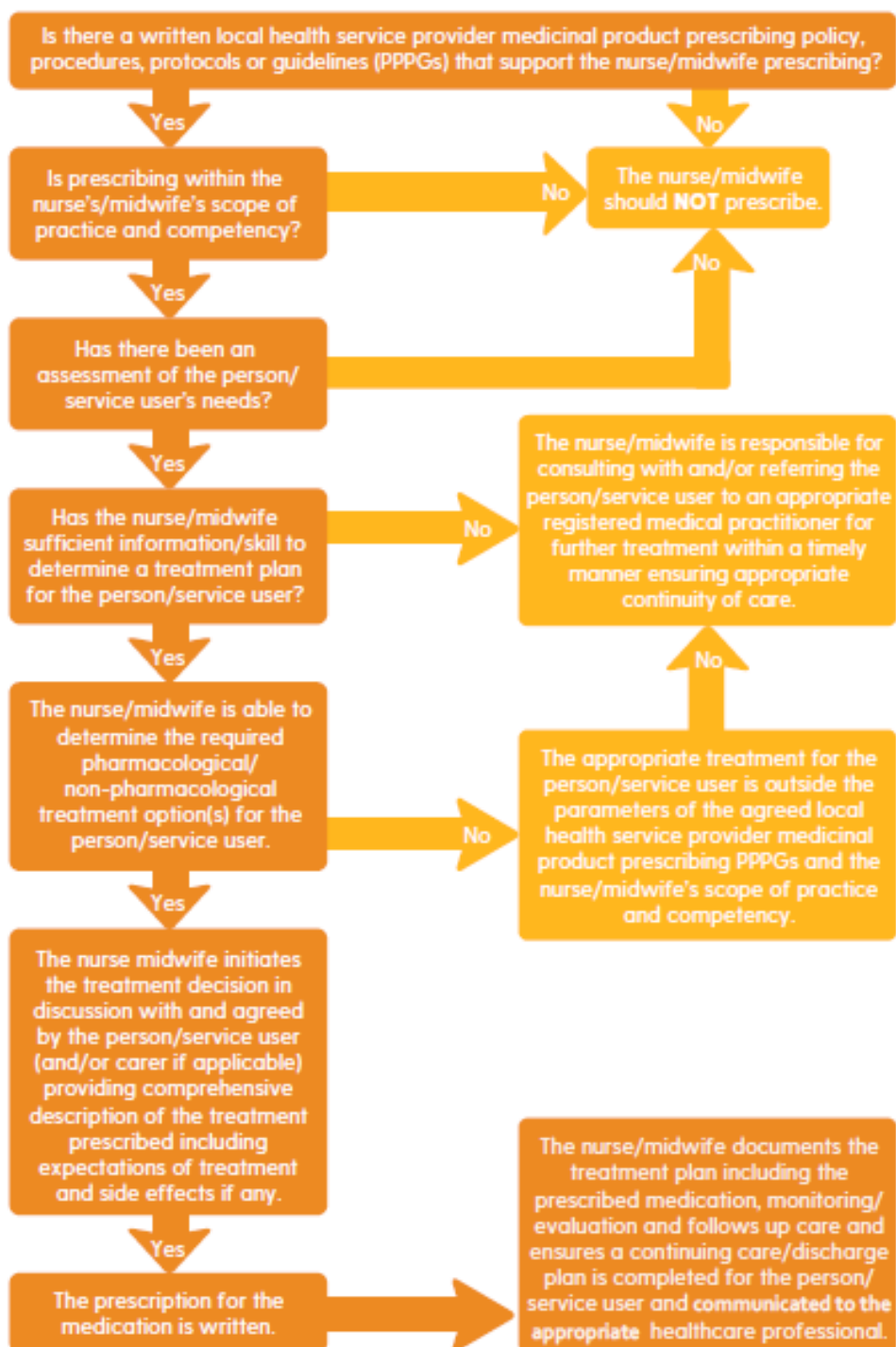
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9.0 Appendices

Appendix I: The Nursing and Midwifery Board of Ireland Decision-making Framework for Nurse and Midwife Prescribing

Appendix 3. Decision-making Framework for Nurse and Midwife Prescribing



Decision-making framework explanatory notes

1. The PPPGs identifies the structures that authorise and provide a framework for the practice of nursing/midwifery prescribing. This may include reference to the involvement of Risk Management and Clinical Governance Committees.
2. Scope of practice and competency:
 - Does the registered nurse or midwife prescriber meet the requirements and standards set by the Nursing and Midwifery Board of Ireland through completion of the education programme for nurse/midwife prescribing?
 - Are they on the Division of the Register of Nurse Prescribers or Midwife Prescribers as maintained by NMBI?
 - Is the RNP/RMP undergoing continuing professional development in prescribing practice to enable competency assessment?
3. Assessment includes:
 - Physical examination
 - History-taking (including medications)
 - Clinical diagnostic decision* (diagnosis, hypothesis)
4. Orders and interprets laboratory and other diagnostic tests – for example, blood test and spirometry.
5. If the person/service user's assessed needs exceed the registered nurse or midwife prescriber's scope of practice, the person/service user is referred to the appropriate registered medical practitioner.
6. Documentation and record-keeping for RNPs/RMPs should be outlined in the local health service provider's PPPGs, for example, prescription writing including prescription pad responsibilities, medication administration record and person/service user's individual case notes; supporting material for clinical audit of the RNP's/RMP's prescribing practice.
7. Continuing care/Discharge plan – Monitoring of therapeutic effect of the prescribed treatment by the registered medical practitioner, RNP/RMP and other team members.

* An example: A registered nurse or midwife with prescriptive authority is working in the diabetic daycare centre. Their patient population includes individuals with known diagnoses of insulin-dependent diabetes. A patient presents with a pattern of hyperglycemia. The registered nurse or midwife prescriber, through their assessment skills, checks for ketones in the urine and for any source of infection. They also enquires about any recent changes in the patient's diet. Based on this information, the registered nurse or midwife prescriber makes a clinical diagnostic decision regarding the elevated blood sugars and the insulin dose is adjusted appropriately.

Appendix II: Principles for Clinical Governance Development

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 manager.
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

Appendix III: Schedule 8

Drugs Which Practitioners Who are Registered Nurses or Registered Midwives May Prescribe within Schedules 2 and 3 (*Misuse of Drugs Regulations, 2017*)

PART 1

Drugs for Pain Relief in Hospital

Drug	Route of Administration
Buprenorphine	Transdermal
Codeine Phosphate	Oral
Dihydrocodeine	Oral
Fentanyl	Intranasal, intravenous, transdermal, transmucosal, subcutaneous, sublingual/buccal
Morphine Sulphate	Intramuscular, intravenous, oral, subcutaneous
Morphine Tartrate	Intramuscular, intravenous, subcutaneous
Oxycodone	Oral, subcutaneous, intravenous
Pethidine	Intramuscular, intravenous, subcutaneous

PART 2

Drugs for Palliative Care

Drug	Route of Administration
Buprenorphine	Transdermal
Codeine Phosphate	Oral
Fentanyl	Intranasal, Intravenous, transdermal, transmucosal, subcutaneous, sublingual/buccal
Hydromorphone	Oral, subcutaneous
Methylphenidate	Oral
Morphine Sulphate	Intramuscular, oral, subcutaneous
Morphine Tartrate	Intramuscular, subcutaneous
Oxycodone	Oral, subcutaneous

PART 3

Drugs for Purposes of Midwifery

Drug	Route of Administration
Pethidine	Intramuscular

PART 4

Drugs for Neonatal Care

Drug	Route of Administration
Fentanyl	Intravenous, transdermal, transmucosal
Morphine Sulphate	Intramuscular, intranasal, intravenous, oral, subcutaneous
Morphine Tartrate	Intramuscular, intravenous, subcutaneous

PART 5

Drugs for Use in Mental Health or Intellectual Disability

Drug	Route of administration
Methylphenidate	Oral

Appendix IV: Sample Commencement Letter

Date *[insert details]*

Name Registered Nurse/Midwife Prescribers *[insert details]*

Clinical Grade *[insert details]*

Ward/Unit/Organisation *[insert details]*

Address 1

Address 2

Address 3

Re: Commencement Date for Registered Nurse or Midwife Medicinal Product Prescriber at *[insert name of Health Service Provider]*

Dear *[insert details]*

Congratulations on registering with the Nursing and Midwifery Board of Ireland as a Registered Nurse/Midwife Prescriber. This marks a milestone in the development of your professional practice. You are now authorised to commence prescribing at *[insert name of Health Service Provider]* from *[insert date]*.

Please note that this authorisation gives you prescriptive authority within your scope of practice and is in compliance with the relevant legislation, professional guidance and regulations in particular the following:

- *HSE National Nurse and Midwife Medicinal Product Prescribing Guideline, 2020*
- *Nursing and Midwifery Board of Ireland (2019) Practice Standards and Guidelines for Nurse and Midwives with Prescriptive Authority, 4th edn*
- *An Bord Altranais (2007) Guidance to Nurses and Midwives on Medication Management.*
- *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007 Misuse of Drugs Regulations 2017 Irish Medicines Board (Miscellaneous Provisions) Act 2006*
- *Nurses and Midwives Rules 2018 (S.I. No. 219/2018-Register of Nurses and Midwives, S.I. No 218/2018-Education and Training).*

As a registered nurse/midwife prescriber you are responsible for maintaining continued professional competence and auditing your prescribing practice in accordance with *[insert name of Health Service Provider]* and the NMBI requirements. The *Nurse and Midwife Prescribing Data Collection System* is available which enables you to input your prescribing activity and run reports and assist you in auditing of your prescribing practice. This is available on the link:

<https://www.nurseprescribing.ie/Login.aspx?ReturnUrl=%2f>

In order to support nurse and midwife prescribers the *Office of the Nursing and Midwifery Service Director (ONMSD)*, has established the following:

- *An email communication mechanism called the Irish-RNP-eNetwork*
- *Access to the Journal of Nurse Prescribing (full text articles)*
- *The Nurse and Midwife Medicinal Product Prescribing Website, click on link <https://healthservice.hse.ie/en/about-us/onmsd/onmsd/specific-programmes/nurse-midwife-medicinal-product-prescribing.html>*

It is important for you to keep up to date with prescribing information of the medicinal products including up-to-date safety information. The Health Products Regulatory Authority (HPRA) publications including articles, drug safety newsletters, and the outcomes of EU safety reviews, new product warnings, details of recalls/suspensions are provided via e-mail or text message to prescribers registered with the HPRA. To register for electronic alerts log onto <http://www.hpra.ie> and follow the links to 'Register'.

I would like to take this opportunity to wish you every success in using your new prescribing competencies within your clinical area of practice.

Yours sincerely,

Director of Nursing/Midwifery/ Relevant Nurse/Midwife Manager

Appendix V: State Claims Agency Statement regarding Nurse Midwife Medicinal Product Prescribing Indemnity



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 the avoidance of any doubt, general practitioners, private nursing homes or other private practice settings and/or their indemnity/insurance providers are not required to extend indemnity cover to registered nurse prescribers authorised to practise in their services. The HSE registered nurse prescriber practicing in these settings, is indemnified by the CIS in respect of the provision of his/her services.

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

January 2018

Appendix VI: State Claims Agency Statement Regarding Prescribing of Exempt and Off-Label Prescribing



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 unauthorised 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.

January 2018

Appendix VII: Application Form Notification and Authorisation of the Community Registered Nurse Prescriber for PCRS Prescription Pads for RN/MP



**Application Form for Notification and Authorisation of
Community Registered Nurse/Midwife Prescriber
(RN/MP)**

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

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 RNP/MP 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 Eligibility & Reimbursement Service (PCERS) has been notified that the RNP/MP 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 / Midwife Prescriber to Complete

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

Insert Details / Comments		
1	RNP name (use block capitals) <ul style="list-style-type: none"> ▪ Forename ▪ Surname ▪ 	
2	Nursing and Midwifery Board of Ireland (NMBI) (PIN)	
3	Date registered as an RNP / MP with NMBI	
4	HSE CHO Area & CHO No.	
5	HSE Statutory /Voluntary Services Employee Number (i.e. personnel number)	
6	Contact address Statutory/Voluntary HSE service where I am employed and from which authorised to prescribe	
7	Contact details <ul style="list-style-type: none"> • Office telephone inc. pre-fix • Mobile • Email 	

8	My clinical area of practice is (for example public health nursing, tissue viability, palliative care etc)	
9	I commit to operating within my scope of practice	
10	I commit to regular audit of my prescribing practice in accordance with Nursing and Midwifery Board of Ireland (2019) Practice Standards and Guidelines for Nurses and Midwives and the Policy for Medicinal Product Prescribing for my service area.	

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 / MP:

Date:

--	--	--	--	--	--	--	--

Part 2: Director of Nursing / Midwifery / Public Health Nursing / Manager or Delegate to Complete

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

Confirmation / Comments	
1	I confirm that the nurse / midwife named in Part 1 of this form is a RNP
2	I confirm that there is a PPPG (Policy, Procedure, Protocols & Guidelines) process for maintaining prescription pad security in the service
3	I confirm that there is a process in place for regular audit of the RNP / MP prescribing practice in accordance with Nursing and Midwifery Board of Ireland (2019) Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority and HSE National Guideline for Nurse and Midwife Medicinal Product Prescribing (2020)

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

**Signature of Director of Nursing / Midwifery /
Public Health Nursing / Manager or Delegate:**

Date:

Part 3: HSE Head of Primary Care / Head of Service to complete

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

Signature of HSE Head of Primary Care / Head of Service:

Date:

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--	--	--	--	--	--	--	--	--	--

CHO No:

Part 4: PCRS to complete (for internal use)

Action	
1	HSE CHO Number
2	GMS Number Assigned
3	Date Issued
4	Details entered
5	PCERS Approval by:

Appendix VIII: Membership of the Guideline Review Group

1. Guideline Review Group Members

Clare Mac Gabhann	National Lead, Director of Nursing and Midwifery (Prescribing)
Maureen Nolan	Director of Nursing, National Lead for the Implementation and Audit of Nurse Prescribing of Ionising Radiation
Rose Lorenz	Assistant Director of Nursing and Midwifery (Prescribing)
Rachael Comer	Assistant Director of Nursing and Midwifery (Prescribing)
Mariette Walsh	Clerical Officer

Appendix IX: Conflict of Interest Declaration Form



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

CONFLICT OF INTEREST DECLARATION

This must be completed by each member of the PPPG Development Group as applicable.

Title of PPPG being considered:

HSE National Nurse and Midwife Medicinal Product Prescribing Guideline

Please circle the statement that relates to you

1. I declare that I DO NOT have any conflicts of interest.
2. I declare that I DO have a conflict of interest.

Details of conflict (Please refer to specific PPPG)

(Append additional pages to this statement if required)

Signature

Printed name

Registration number (if applicable)

Date

This information provided will be processed in accordance with data protection principles as set out in the Data Protection Act. Data will be processed only to ensure that committee members act in the best interests of the committee. The information provided will not be used for any other purpose.


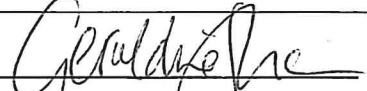
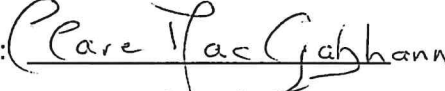
A person who is covered by this PPPG is required to furnish a statement, in writing, of:

(i) The interests of the person, and

(ii) The interests, of which the person has actual knowledge, of his or her spouse or civil partner or a child the person or of his or her spouse which could materially influence the person in, or in relation to, the performance of the person's official functions by reason of the fact that such performance could so affect those interests as to confer on, or withhold from, the person, or the spouse or civil partner or child, a substantial benefit.

Appendix X: Membership of the Approval Governance Group

Please list all members of the relevant approval governance group (and title) who have final approval of the PPPG document.

Dr Colm Henry Chief Clinical Officer, HSE	Signature: <u></u> Date: <u>28.05.20</u>
Dr Geraldine Shaw Nursing and Midwifery Services Director, Office of the Nursing & Midwifery Services Director (ONMSD), Office of the Chief Clinical Officer (CCO), HSE	Signature: <u></u> Date: <u>15.04.2020</u>
Chairperson: Clare Mac Gabhann National Lead, Director of Nursing and Midwifery (Prescribing), Office of the Nursing & Midwifery Services Director (ONMSD), Office of the Chief Clinical Officer (CCO), HSE	Signature: <u></u> Date: <u>14TH APRIL 2020</u>

Appendix XI: Glossary of Terms

- **Adverse Reaction:** A response to a medicinal product which is noxious and unintended [DIR 2001/83/EC Art 1 (11)].
- **Authorised Medicinal Product:** A medicinal product which is authorised (or registered, in the case of homeopathic and certain herbal medicinal products) by the HPRA to be marketed in Ireland, or by the European Commission (following a common EU assessment procedure co-ordinated by the European Medicines Agency (EMA)) to allow medicinal products to be placed on the markets in EU Member States. Under European and Irish legislation, all medicinal products must be authorised (or registered) before being placed on the market (Directive 2001/83/EC).
- **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 who 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 the NMBI. (An Bord Altranais, 2007).
- **Clinical Audit:** The *Commission on Patient Safety and Quality Assurance* (2008, page 152) defines clinical audit as '*a clinically led, quality improvement process that seeks to improve patient care and outcomes through the systematic review of care against explicit criteria and to act to improve care when standards are not met*'. In essence, clinical audit is the process of assessing clinical practice against standards (HSE, 2013).
- **Clinical Governance:** Clinical governance is a framework through which healthcare teams are accountable for the quality, safety and satisfaction of patients in the care they deliver. It is built on the model of the Chief Executive Officer (CEO)/ General Manager (GM) or equivalent working in partnership with the Clinical Director, Director of Nursing/Midwifery and Service Manager. A key characteristic of clinical governance is a culture and commitment to agreed service levels and quality of care to be provided.
- **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 or registered medicinal products and off-label prescribing providing the latter is used with the expressed knowledge and consent of the enterprises management.
- **Competence:** The ability of a RNP to practice safely and effectively, fulfilling their professional responsibility within their scope of practice (NMBI, 2014).
- **Controlled Drug:** A substance which has the potential for abuse and is controlled under the *Misuse of Drugs Acts 1977 – 2016* and *Misuse of Drugs Regulations 2017*.
- **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 PCRS.

- **Drugs and Therapeutics Committee (D&T):** D&T Committees have an oversight function in their role of assurance for appropriate patient drug therapy and outcomes. This supports the promotion of safe patient care. It is the responsibility of the health service provider to ensure clinical governance structures are in place in relation to prescribing for all prescribers.
- **European Medicines Agency (EMA)** An agency of the European Union, located in Amsterdam. The Agency is responsible for the scientific evaluation of medicinal products developed by pharmaceutical companies for use in the European Union. The Agency is responsible for the co-ordination of the scientific evaluation of applications for European marketing authorisations for both human and veterinary medicinal products (centralised procedure). Under the centralised procedure, companies submit a single marketing authorisation application to the Agency. Once granted by the European Commission, a centralised (or community) marketing authorisation is valid in all European Union and EEA-EFTA states (Iceland, Liechtenstein and Norway).
- **Exempt Medicinal Product (EMP):** An exempt medicinal product (EMP) is a medicinal product that is not authorised or registered in Ireland either by the HPRA or in the case of a centrally authorised medicinal product, by the European Commission (via the European Medicines Agency), but which can be legally supplied in response to a *bona fide* unsolicited order, formulated in accordance with the specifications of a registered medical practitioner or registered dentist for use by their individual patients on her/his direct personal responsibility, in order to fulfil the special needs of those patients (Ref. *Medicinal Products (Control of Placing on the Market) Regulations, 2007, as amended.*) This legislation provides statutory authority for a medical practitioner to treat a patient under her/his care, using exempt medicinal products. The enactment of S.I. No. 529 of 2018 now provides the authority for the prescribing of exempt medicinal products by RN/MP's.
- **General Medical Services Scheme (GMS):** Persons who are unable without undue hardship to arrange GP, 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 PCRS.
- **Generic Medicinal Product:** This 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 Non-proprietary 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.
- **Governance:** In health care, an integration of corporate and clinical governance; the systems, processes and behaviours by which services lead, direct and control their functions in order to achieve their objective, including the quality and safety of services for service users. (Health Information and Quality Authority, 2012).
- **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 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.
- **Incident:** An event or circumstance which could have, or did lead to unintended and/or unnecessary harm. Incidents include adverse events which result in harm; near misses which could have resulted in harm, but did not cause harm, either by chance or timely intervention; and staff or service user complaints which are associated with harm. Incidents can be clinical or non-clinical and include incidents associated with harm to:
 - Patients, Service users, Staff and visitors
 - the attainment of HSE objectives
 - ICT systems
 - Data security e.g. data protection breaches
 - the environment (HSE, 2018)Patients, Service users, Staff and visitors
- **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.
- **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 GP 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).
- **National Incident Management System (NIMS):** The NIMS, hosted by the CIS, is a highly secure web-based database which facilitates direct reporting of adverse events by State authorities and healthcare enterprises; it is the single designated

system for reporting of all incidents in the public healthcare system i.e. for HSE and HSE funded services.

- **National Incident Reporting Form (NIRF):** The NIRF was developed by the State Claims Agency in conjunction with all stakeholders including the HSE and voluntary hospitals. Use of a NIRF assures the accuracy of data and clarity of information being reported. There are four forms in total; Person, Property, Crash/Collision and Dangerous Occurrences (Reportable Circumstances)/Complaints.
- **Near Miss:** An incident that was prevented from occurring due to timely intervention or chance and which there are reasonable grounds for believing could have resulted, if it had not been so prevented, in unintended or unanticipated injury or harm to a service user during the provision of a health service to that service user(HSE, 2018)
- **Off-label Use:** Off-label use refers to the use of an authorised medicinal product outside the terms of its marketing authorisation or product registration. It is the prescribing of the medicinal product that is off-label, rather than the medicinal product itself.
- **Open Disclosure** Open disclosure is defined as an open, consistent, compassionate and timely approach to communicating with patients and, where appropriate, their relevant person following patient safety incidents. It includes expressing regret for what has happened, keeping the patient informed and providing reassurance in relation to on-going care and treatment, learning and the steps being taken by the health services provider to try to prevent a recurrence of the incident. (HSE, 2019)
- **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, subject to Regulation 3, by a registered nurse or registered midwife for medical treatment of an individual (*Misuse of Drugs Regulations 2017*).
- **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 ONMSD (team with responsibility for implementing the initiative).
- **Product Authorisation (PA):** A marketing authorisation (i.e. licence) to market a medicinal product granted by the Health Product Regulatory Authority (formally Irish Medicines Board) in accordance with Article 7 of the Medicinal Products (*Licensing and Sale Regulations*, 1998). The product information/packaging for medicines which hold product authorisations granted by the HPRA carry a Product Authorisation (PA) number. The product information/packaging for centrally authorised medicines authorised by the EU Commission carry an EU authorisation number.
- **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 (RNP):** ‘A nurse or midwife who is registered in the Division of the Register of Nurse Prescribers of An Bord Altranais’ (An Bord Altranais, 2007). RN/MP is used throughout this document to include registered nurse/midwife prescribers.
- **Schedule 8:** A detailed listing of the drugs, route of administration and condition for which Schedule 2 or 3 medications can be prescribed by the registered nurse prescriber. (*Misuse of Drugs Regulation 2017*) (Appendix II).
- **Site Declaration Form:** A form completed by the Director of Nursing/Midwifery and signed by the medical mentor confirming the governance requirements for nurse and midwife medicinal product prescribing are in place in advance of each applicant undertaking the education programme. This form is part of the application process for all Higher Education Institutes (HEIs).
- **Summary of Product Characteristics (SmPC):** The authorised product information is comprised of the Summary of Product Characteristics (SmPC) and the Package Leaflet (PL). The SmPC and PL are issued when a medicine is first licensed for use and are reviewed and updated as necessary throughout the lifetime of the medicine. The SmPC is mainly intended for use by healthcare professionals and includes detailed information on the use, dosing recommendations, precautions for use and the known side-effects of the medicine concerned. SmPCs for all products currently authorised in Ireland are accessible from the HPRA website (www.hpra.ie). The PL reflects the more comprehensive information described in the SmPC, but is required to be presented in an abbreviated and easy-to-read format for patients.

Appendix XII: Approved Policies, Procedures, Protocols and Guidelines Checklist

Standards for Developing Clinical PPPG	Checklist
Stage 1 Initiation	
<p>The decision making approach relating to the type of PPPG guidance required (policy, procedure, protocol, guideline), coverage of the PPPG (national, regional, local) and applicable settings are described.</p>	<input type="checkbox"/>
<p>Synergies/co-operations are maximised across departments/organisations (Hospitals/Hospital Groups/Community Healthcare Organisations (CHO)/National Ambulance Service (NAS)), to avoid duplication and to optimise value for money and use of staff time and expertise.</p>	<input type="checkbox"/>
<p>Title: National Nurse and Midwife Medicinal Product Prescribing Guideline 2020</p> <p>The scope of the PPPG is clearly described, specifying what is included and what lies outside the scope of the PPPG.</p>	<input type="checkbox"/>
<p>The target users and the population/patient group to whom the PPPG is meant to apply are specifically described.</p>	<input type="checkbox"/>
<p>The views and preferences of the target population have been sought and taken into consideration (as required).</p>	<input type="checkbox"/>
<p>The overall objective(s) of the PPPGs are specifically described.</p>	<input type="checkbox"/>
<p>The potential for improved health is described (e.g. clinical effectiveness, patient safety, quality improvement, health outcomes, quality of life, quality of care).</p>	<input type="checkbox"/>
<p>Stakeholder identification and involvement: The PPPG Development Group includes individuals from all relevant stakeholders, staff and professional groups.</p>	<input type="checkbox"/>
<p>Conflict of interest statements from all members of the PPPG Development Group are documented, with a description of mitigating actions if relevant.</p>	<input type="checkbox"/>
<p>The PPPG is informed by the identified needs and priorities of service users and stakeholders.</p>	<input type="checkbox"/>

There is service user/lay representation on PPPG Development Group (as required).	<input checked="" type="checkbox"/>
Information and support is available for staff on the development of evidence-based clinical practice guidance.	<input checked="" type="checkbox"/>
Stage 2 Development	Checklist
The clinical question(s) covered by the PPPG are specifically described.	<input checked="" type="checkbox"/>
Systematic methods used to search for evidence are documented (for PPPGs which are adapted/adopted from international guidance, their methodology is appraised and documented).	<input checked="" type="checkbox"/>
Critical appraisal/analysis of evidence using validated tools is documented (the strengths, limitations and methodological quality of the body of evidence are clearly described).	<input checked="" type="checkbox"/>
The health benefits, side effects and risks have been considered and documented in formulating the PPPG.	<input checked="" type="checkbox"/>
There is an explicit link between the PPPG and the supporting evidence.	<input checked="" type="checkbox"/>
PPPG guidance/recommendations are specific and unambiguous.	<input checked="" type="checkbox"/>
The potential resource implications of developing and implementing the PPPG are identified e.g. equipment, education/training, staff time and research.	<input checked="" type="checkbox"/>
There is collaboration across all stakeholders in the planning and implementation phases to optimise patient flow and integrated care.	<input checked="" type="checkbox"/>
Budget impact is documented (resources required).	<input checked="" type="checkbox"/>
Education and training is provided for staff on the development and implementation of evidence-based clinical practice guidance (as appropriate).	<input checked="" type="checkbox"/>

<p>Three additional standards are applicable for a small number of more complex PPPGs:</p> <p>Cost effectiveness analysis is documented.</p> <p>A systematic literature review has been undertaken.</p> <p>Health Technology Assessment (HTA) has been undertaken.</p>	<p>Not deemed necessary</p> <p><input checked="" type="checkbox"/></p> <p>Not undertaken</p>
Stage 3 Governance and Approval	Checklist
Formal governance arrangements for PPPGs at local, regional and national level are established and documented.	<input checked="" type="checkbox"/>
The PPPG has been reviewed by the independent experts prior to publication (as required).	<input checked="" type="checkbox"/>
Copyright and permissions are sought and documented.	<input checked="" type="checkbox"/>
Stage 4 Communication and Dissemination	Checklist
A communication plan is developed to ensure effective communication and collaboration with all stakeholders throughout all stages.	<input checked="" type="checkbox"/>
Plan and procedure for dissemination of the PPPG is described.	<input checked="" type="checkbox"/>
The PPPG is easily accessible by all users e.g. PPPG repository.	<input checked="" type="checkbox"/>
Stage 5 Implementation	Checklist
Written implementation plan is provided with timelines, identification of responsible persons/units and integration into service planning process.	<input checked="" type="checkbox"/>
Barriers and facilitators for implementation are identified, and aligned with implementation levers.	<input checked="" type="checkbox"/>
Education and training is provided for staff on the development and implementation of evidence-based PPPG (as required).	<input checked="" type="checkbox"/>
There is collaboration across all stakeholders in the planning and implementation phases to optimise patient flow and integrated care	<input checked="" type="checkbox"/>

Stage 6 Monitoring, Audit, Evaluation	Checklist
Process for monitoring and continuous improvement is documented	<input type="checkbox"/>
Audit criteria and audit process/plan are specified	<input type="checkbox"/>
Process for evaluation of implementation and (clinical) effectiveness is specified.	<input type="checkbox"/>
Stage 7 Revision/Update	Checklist
Documented process for revisions/updating and review, including timeframe is provided.	<input type="checkbox"/>
Documented process for version control is provided.	<input type="checkbox"/>

I confirm that the above Standards have been met in developing the following:

Title of PPPG: HSE National Nurse and Midwife Medicinal Product Prescribing Guideline 2020

Name of person signing off on the PPPG Checklist: _____

Title of person signing off on the PPPG Checklist: _____

Signature of person signing off on the PPPG Checklist: _____

Date: _____

Name of Person signing off on the PPPG Checklist: _____

This signed PPPG Checklist must accompany the final PPPG document in order for the PPPG to be approved.

