National Nurse and Midwife Medicinal Product Prescribing Policy

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

Changing practice to support service delivery
# National Nurse and Midwife Medicinal Product Prescribing Policy

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

This document is a Policy

<table>
<thead>
<tr>
<th>Title of Policy Development Group:</th>
<th>ONMSD Nurse and Midwife Medicinal Product Prescribing Team</th>
</tr>
</thead>
</table>
| Approved By:                      | Dr Áine Carroll, National Director of Clinical Strategy and Programmes, HSE  
|                                   | Ms Mary Wynne, Interim Nursing and Midwifery Services Director, HSE |
| Reference Number:                 | ONMSD 2018-015                                           |
| Version Number:                   | 3                                                         |
| Publication Date:                 | 2018                                                     |
| Date for Revision:                | 2021                                                     |
| Electronic Location:              | www.hse.ie/go/nurseprescribing                           |

<table>
<thead>
<tr>
<th>Version</th>
<th>Date Approved</th>
<th>List Section Numbers Changed</th>
<th>Author</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This is a controlled document: While this document may be printed the electronic version posted on the website is the controlled copy and can only be guaranteed for 24 hours after downloading.
TABLE OF CONTENTS

PART A ............................................................................................................................................... 4
INTRODUCTION ....................................................................................................................................... 4
LEGISLATION, ASSOCIATED REGULATION AND RULES ........................................................................... 4
PROFESSIONAL REGULATION ............................................................................................................... 5
IMPLEMENTATION ..................................................................................................................................... 6

1.0 OUTLINE OF POLICY STEPS ............................................................................................................. 6
1.1 CHIEF EXECUTIVE OFFICER/CHIEF OFFICER/GENERAL MANAGER OR OTHER SENIOR MANAGER WITHIN THE HEALTH SERVICE PROVIDER ........................................................................................................................................ 6
1.2 THE DIRECTOR OF NURSING/MIDWIFERY/OR RELEVANT NURSE MIDWIFE MANAGER (REFERRED TO HEREAFTER AS THE DIRECTOR) .................................................................................................................................................. 7
1.3 LINE MANAGER OF CANDIDATE OR REGISTERED NURSE PRESCRIBER ........................................................................................................................................ 8
1.4 PRESCRIBING SITE COORDINATOR ...................................................................................................... 8
1.5 POTENTIAL APPLICANTS ..................................................................................................................... 9
1.6 CANDIDATE NURSE OR MIDWIFE PRESCRIBER .................................................................................. 9
1.7 REGISTERED NURSE PRESCRIBER ...................................................................................................... 9
1.8 THE MEDICAL MENTOR ....................................................................................................................... 10
1.9 THE COLLABORATING MEDICAL PRACTITIONER(S) .......................................................................... 10
1.10 THE PHARMACIST ............................................................................................................................ 11
1.11 THE DRUGS AND THERAPEUTICS COMMITTEE OR REVIEW GROUP .................................................. 11

2.0 ELIGIBILITY TO PRESCRIBE .............................................................................................................. 12
2.1 VALIDATION OF THE COLLABORATIVE PRACTICE AGREEMENT AND REGISTRATION WITH THE NMBI .................................................................................................................................................. 12
2.2 TERMINATION OF THE COLLABORATIVE PRACTICE AGREEMENT ...................................................... 13

3.0 PRESCRIPTION WRITING ................................................................................................................... 13
3.1 PRESCRIPTION WRITING FOR CONTROLLED DRUGS ......................................................................... 14
3.2 REPEAT PRESCRIPTION VERSUS INSTALMENT .................................................................................. 15

4.0 PRESCRIBING FOR OFF-LABEL USE AND EXEMPT MEDICINAL PRODUCTS ........................................ 16
4.1 PRESCRIBING FOR OFF-LABEL USE ................................................................................................... 16
4.2 EXEMPT MEDICINAL PRODUCTS .................................................................................................... 16

5.0 SECURITY AND SAFE HANDLING OF PRESCRIPTION PADS .................................................................. 17

6.0 ADVERSE REACTIONS AND MEDICATION ERRORS/NEAR MISSES .................................................. 17
6.1 ADVERSE REACTIONS ....................................................................................................................... 17
6.2 MEDICATION ERRORS/NEAR MISSES ............................................................................................... 18

7.0 THE STATE CLAIMS AGENCY CLINICAL INDEMNITY SCHEME ....................................................... 19

8.0 COMMUNITY DRUG PRESCRIBING ................................................................................................... 19
8.1 COMMUNITY DRUG PRESCRIBING SCHEMES ............................................................................... 19
8.2 PRIMARY CARE PRESCRIPTION FORM .............................................................................................. 19

PART B ...................................................................................................................................................... 20

1.0 INITIATION .......................................................................................................................................... 20
1.1 PURPOSE ........................................................................................................................................... 20
1.2 SCOPE ............................................................................................................................................... 20
1.3 AIM AND OBJECTIVES ....................................................................................................................... 20
1.3.1 Aim ............................................................................................................................................... 20
PART A

Introduction
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 policies and guidelines.

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

Health service providers introducing nurse and midwife medicinal product prescribing should be cognisant of the Principles for Clinical Governance Development (HSE, 2012) (Appendix I). This framework supports health care teams who are accountable for the quality and safety in the care they deliver to their patients/service users.

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

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 (Statutory Instruments No. 3 of 2006) contains an enabling provision for the extension of prescriptive authority for nurses and midwives. Following public consultation undertaken by the Department of Health and Children the following were signed into law:

- Irish Medicines Board (Miscellaneous Provision) Act 2006 (Statutory Instruments No. 3 of 2006)
- Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007, (Statutory Instruments No. 201 of 2007)
- Nurses Rules (An Bord Altranais, 2010)
- Nurses and Midwives Rules (Nursing and Midwifery Board of Ireland, 2013).

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:


Further regulatory changes were also made to support Nursing and Midwifery Medicinal Product Prescribing:
• Nurses and Midwives Act (2011) (Statutory Instruments 41 of 2011)
• Nurses Rules (2010) (Statutory Instruments 689 of 2010)
• Nurses and Midwives Rules (2013) (Statutory Instruments 435 of 2013) (Supplemental to 2010 Nurses Rules)
• Misuse of Drugs Regulations 2017, (Statutory Instruments No. 173 of 2017). This revokes 2007 regulations.

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
• Nursing and Midwifery Board of Ireland (NMBI) registration number (also known as the Personal Identification Number (PIN)) must be stated on the prescription.

The regulations do not restrict an employer from imposing conditions including prohibiting a nurse or midwife from prescribing. The prescribing of controlled drugs is detailed in the Misuse of Drugs Regulation 2017 (MDA), which stipulates conditions for establishing a separate Schedule 8 and restriction for prescribing Schedule 2 and 3 medicinal products.

Professional Regulation
This policy adheres to the regulatory framework and has been developed in conjunction with the guidance issued by the NMBI including:

• Collaborative Practice Agreement for Nurses and Midwives with Prescriptive Authority 4th edn (NMBI, 2016)
• Prescriptive Authority for Nurses and Midwives Standards and Requirements (NMBI 2015)
• Scope of Nursing and Midwifery Practice Framework (NMBI, 2015)
• Code of Professional Conduct and Ethics for Registered Nurses and Midwives (NMBI, 2014)
• Practice Standards for Midwives (NMBI, 2015)
• Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority, 3rd edn (NMBI, 2018)
• Guidance to Nurses and Midwives on Medication Management (An Bord Altranais, 2007).

The name An Bord Altranais was changed following the signing of Commencement Order Statutory Instruments 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).
Implementation
The ONMSD is responsible for leading the national implementation of nurse and midwife medicinal product prescribing in Ireland. A suite of documents to support the initiative is available at the following link www.hse.ie/go/nurseprescribing

1.0 Outline of Policy Steps
The health service provider must clearly differentiate between the functions of line management and clinical governance for nurse and midwife medicinal product prescribing. Where the RNP’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 RNP can refer for professional nursing or 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 participate in 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, Group Director of Nursing and Midwifery) 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 or relevant nurse or midwife manager, the strategic direction of nurse or midwife medicinal product prescribing in their Health Service Provider and provide the structures required for safe and appropriate prescribing
- Ensuring that the vesting of prescriptive authority for nurses and midwives is included within the overall clinical governance structure of primary, community and hospital services and delegates responsibility appropriately to relevant healthcare professionals.
1.2 The Director of Nursing/Midwifery/or Relevant Nurse Midwife Manager (Referred to hereafter as the Director)

The Director is responsible for:

- Planning the strategic direction for nurse and midwife medicinal product prescribing in line with national and local policy
- Informing medical mentors and collaborating medical practitioners of their role in nurse and midwife medicinal product prescribing
- Delegating responsibilities as deemed appropriate
- Signing the Site Declaration Form on behalf of the respective Health Service Provider and in so doing commits to ensuring that the following structures are in place.

**Safe management**

- Ensuring the *HSE National Policy for Nurse and Midwife Medicinal Product Prescribing* is in place
- Ensuring risk management systems and processes are in place for reporting of adverse event, incidents, near misses and medication errors

**Practice and Education Development**

- Ensuring robust and agreed collaborative practice arrangements are in place
- Ensuring appropriate mentoring arrangements with a named mentor are in place
- Ensuring a named medical practitioner(s) who have agreed to develop the collaborative practice arrangements are identified
- Ensuring the name of the nurse or midwife applying for the education programme is on the active register of nurses and midwives maintained by the NMBI

**Health Service Provider**

- Ensuring arrangements are in place to oversee the introduction of nurse and midwife medicinal product prescribing
- Ensuring access to a Drugs and Therapeutics (D&T) Committee or Review Group
- Ensuring a named individual is identified with responsibility for the initiative locally and for liaising with the education provider, NMBI and the Office of the Nursing and Midwifery Services Director (ONMSD) prescribing team. This person is known as the Prescribing Site Coordinator (PSC)
- Ensuring access to a computer, email and internet for data input to the *Nurse and Midwife Prescribing Data Collection System*, where required
- Ensuring sponsorship arrangements at local level, setting out study leave and financial agreement for the candidate nurse/midwife prescriber are in place

**Audit and Evaluation**

- Ensuring 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 and midwife medicinal product prescribing
- Ensure that all entrants to the medicinal product prescribing education programme are selected according to identified service need
- Identify a timeframe for approval of the Collaborative Practice Agreement (CPA) within three months of successfully completing the education programme as outlined in the Site Declaration Form.
- Agree on a timeframe for review of the CPA as per local policy
- Support the submission of relevant documentation by the candidate to the NMBI to register as a RNP within two weeks of approval of the CPA as outlined in the Site Declaration Form
- Notify the RNP of a commencement date for prescriptive authority within their service area on receipt of confirmation of registration from the NMBI
- Ensure that arrangements are in place to provide access to continuing professional development for all nurse and midwife prescribers
- Address identified issues or breaches of the RNPs prescribing practices
- In cases where it is necessary to suspend the RNP prescribing authority, the Director will inform the NMBI and other relevant stakeholders
- Provide reports pertaining to nurse and midwife medicinal product prescribing as required.

1.3 Line Manager of Candidate or Registered Nurse Prescriber

The Line Manager is responsible for:

- In consultation with the multidisciplinary team and the Director, identifying the service need for nurse or midwife medicinal product prescribing
- In consultation with the Director and PSC, identifying appropriate candidate(s) to undertake the education programme and supporting the application process
- Supporting the continuing professional development of the candidate/RNP
- Informing the Director of any issues associated with the RNP prescribing practices and taking appropriate action
- Supporting audit and responding appropriately to audit reports undertaken of the RNP’s prescribing practices.

1.4 Prescribing Site Coordinator

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

- Co-ordinating and supporting nurse and midwife medicinal product prescribing at service level
- Ensuring compliance with the requirements and standards of the NMBI and the HSE
- Acting as a central point of contact for the candidate, RNP, mentor, collaborating medical practitioners, D&T Committee/Review Group, pharmacist and key stakeholders, and communicating all matters in relation to nurse and midwife medicinal product prescribing where necessary
- Facilitating the submission of the CPA for review to the D&T Committee or Review Group by the candidate nurse/midwife prescriber/RNP
- Supporting audit and responding appropriately to audit reports undertaken on the RNPs prescribing practices.
1.5 Potential Applicants
Potential applicants must:

- Ensure they are registered on the active register of nurses and midwives maintained by the NMBI
- Seek the approval of the Director to apply for the education programme
- Comply with the *Nurse and Midwife Prescribing Application Guidelines for the Education Programmes* (HSE, 2018).

1.6 Candidate Nurse or Midwife Prescriber
The candidate nurse or midwife prescriber must:

- Comply with sponsorship arrangements at local level, setting out study leave and financial agreement
- Successfully complete an approved education programme
- Liaise with the PSC on their progress as required
- In consultation with the collaborating medical practitioner(s), complete the CPA and submit it to the D&T Committee or Review Group for review within the timeframe outlined in the Site Declaration Form
- Discuss with the Director and the PSC any situations where these responsibilities cannot or are not being fulfilled.

1.7 Registered Nurse Prescriber
The RNP must:

- Ensure his/her name is entered in the Nurse Prescribers Division of the Register of the NMBI
- Hold full accountability and professional responsibility for all aspects of their prescribing practice
- Practice within a framework of professional accountability and legal boundaries
- Have a valid CPA in place with the Collaborating Medical Practitioner(s). The RNP can only prescribe for patients of Collaborating Medical Practitioner/s with whom a CPA is in place
- Commit to, and undertake, continuing professional development to maintain his/her competence for prescriptive authority
- Inform the Director, his/her line manager and the PSC of any concerns pertaining to his/her competence
- Participate in audit and other quality assurance processes
- Utilise the *Nurse and Midwife Prescribing Data Collection System* if required as per local health service provider policy
- Review and/or revise the CPA as per local policy, in collaboration with the PSC and collaborating medical practitioner(s)
- 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 and 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 products: www.hpра.ie
• Inform the NMBI, in writing, within five working days of the termination of a CPA and provide the reason for its termination (e.g. resignation or change of employment) ([https://www.nmbi.ie](https://www.nmbi.ie))
• Inform relevant stakeholders when CPA is terminated/renewed/recommenced as per NMBI CPA Guidelines
• Discuss with the 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 2018) requires the nurse or midwife prescriber to effectively and efficiently communicate with the patient / service user and to complete an accurate and comprehensive medication history. The nurse or midwife prescriber should only prescribe if they have appropriately assessed the patient / service user and has a valid clinical relationship with the patient / service user.

The nurse or midwife prescriber should communicate clearly with the patient / service user in a language that they understand. Patient / service user should normally be provided with information 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 (An Bord Altranais, 2007; NMBI, 2018).

1.8 **The Medical 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 or 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 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)
• At the end of the education programme, completing and ‘signing off’ the candidate’s Competency Booklet/Mentor Declaration. The candidate must pass the clinical component in order to successfully complete the education programme.

1.9 **The Collaborating Medical Practitioner(s)**

The Collaborating Medical Practitioner is a medical practitioner or group of medical practitioners with whom the RNP has a valid CPA as part of the requirements to prescribe
medicinal products within his/her scope of practice. The responsibilities of the Collaborating Medical Practitioner(s) are as follows:

- Support nurse and midwife medicinal product prescribing
- In collaboration with the candidate/RNP, develop and sign the CPA
- Agree communication and referral mechanisms with the RNP
- Where a HSE RNP has a CPA with a group GP practice, the lead GP in the practice may discuss nurse and midwife medicinal product prescribing with their colleagues and, with their approval, may sign the CPA on behalf of the practice. The lead GP has the responsibility to inform GPs/locums of the practice’s commitment to and participation in nurse and midwife medicinal product prescribing
- Where a RNP has a CPA with a number of medical practitioners, the lead practitioner may discuss nurse and midwife medicinal product prescribing with their colleagues and, with their approval, may sign on behalf of the other medical practitioners. The lead practitioner has the responsibility to inform the other practitioner/locums or new consultants of the health service provider’s commitment and involvement to nurse and midwife medicinal product prescribing
- The collaborating medical practitioner(s) should be aware of the professional regulatory, HSE and Health Service Provider requirements for nurse and midwife medicinal product prescribing
- Where possible, the collaborating medical practitioner(s) participates in the monitoring and auditing of RNPs medicinal product prescribing practices.

1.10 The Pharmacist
The pharmacist provides patient centred medicines information to all staff involved in medicines management on a daily basis. The provision of information and advice by pharmacists is important in promoting evidence-based high quality prescribing, which is a key objective of nurse and midwife prescribers, pharmacists and all prescribers.

1.11 The Drugs and Therapeutics Committee or Review Group
It is strongly recommended that each Health Service Provider has a D&T committee in place, or has access to one. In the absence of a D&T committee, a Review Group may be established with specific terms of reference for nurse and midwife medicinal product prescribing. Where a Review Group is established, it must include, at a minimum representation from senior nursing and/or midwifery, medical and pharmacy personnel.

The following points should be considered by the D&T Committee or Review Group in respect of nurse and midwife medicinal product prescribing:

- Review and advise on the medicinal product listing of the CPA and provide feedback to the candidate/RNP and the Director
- Ensure the medicinal product is:
  - written in generic format where possible
  - authorised by the HPRA or in the case of centrally authorised medicinal product, by the European Medicines Agency (EMA)
- Review and advise on any additions and/or amendments to the medicinal products listing proposed by the candidate/RNP
- Support timely registration of the candidate nurse/midwife prescriber; agree where appropriate to communicate electronically. This enables review in the absence/deferral of face to face meetings
• Where appropriate, receive and/or review audit reports of the RNP’s prescribing practices
• If the medicinal product is prescribed for off label use, review the supporting documentation submitted by the candidate/RNP for the inclusion of the medicinal product on the CPA. Refer to the Nurse and Midwife Medicinal Product Prescribing Toolkit: Authorised Medicinal Products, Off-label Prescription and Exempt Medicinal Products Toolkit (HPRA and HSE, 2017).

For further information regarding D&T committee please refer to Nurse and Midwife Medicinal Product Prescribing Toolkit: Drugs and Therapeutics Committee (NMBI, HSE, 2017)

2.0 Eligibility to Prescribe

2.1 Validation of the Collaborative Practice Agreement and Registration with the NMBI
Prescriptive authority for the RNP extends only to those medicinal products normally prescribed in the named clinical area, listed in the CPA, in consultation with the collaborating medical practitioner/s and authorised by the Director.

• The candidate nurse/midwife prescriber must prepare the CPA in consultation with the collaborating medical practitioner(s) in accordance with NMBI guidelines
• The candidate nurse/midwife prescriber must ensure that all sections of the CPA are correctly completed and fully edited prior to submission to the D&T Committee or Review Group and the Director
• The CPA which incorporates the list of medicinal products that will be prescribed, is submitted to the D&T Committee or Review Group for review as per local policy
• When the CPA has been reviewed by the D&T Committee or Review Group, the PSC or candidate nurse or midwife prescriber, forwards the copy signed by the candidate/RNP and the Collaborating Medical Practitioner to the Director for approval
• The Director, on behalf of the Health Service Provider, then authorises and signs the CPA
• The candidate nurse prescriber submits the following to the NMBI to have their name entered in the Division of Registered Nurse Prescribers:
  o the completed signed and stamped Application Form for Registration in the Registered Nurse Prescribers Division of the Register
  o the relevant registration fee
• Confirmation letters of registration as a RNP are then sent to the individual nurse or midwife and to the Director/employer by the NMBI
• The Director, on behalf of the Health Service Provider, informs the RNP, in writing, of the commencement date on which they are authorised to commence prescribing (Appendix III)
• Original copies of the valid CPA and copies of the NMBI registration are maintained in the RNP’s personnel file. The RNP should also retain a copy of the valid CPA
• The CPA is reviewed at a minimum every three years or within a timeframe determined by the Health Service Provider
• Changes/additions to the list of medicinal products must be agreed with the Collaborating Medical Practitioner/s, reviewed by the D&T committee or Review Group and approved by the Director.
2.2 Termination of the Collaborative Practice Agreement

The CPA is terminated if the RNP or the collaborating medical practitioner(s) resigns from their post. Where there is more than one collaborating medical practitioner, the CPA is valid for the remaining collaborating medical practitioners listed on the CPA.

- The CPA will be deemed invalid on the termination, transfer or movement of the RNP from the post for which it was originally developed.
- The CPA is subject to review, suspension and possible termination if the RNP or collaborating medical practitioner is subject to disciplinary action or fitness to practice review by their regulatory body.
- The CPA terminates automatically if the RNP or collaborating medical practitioner no longer has an active unrestricted registration.
- In the event of a termination of a CPA, the RNP will notify the Director and the NMBI, within five working days of the termination and also provide the reason/s for its termination (e.g. resignation or change of employment).
- *Termination of the Collaborative Practice Agreement Form* must be completed and sent to NMBI by RNP [www.nmbi.ie](http://www.nmbi.ie).

3.0 Prescription Writing

Specific standards for prescription writing must be adhered to as required by legislation and the Health Service Provider/employer. This also pertains to the safe keeping and accountability associated with prescription pads.

Medicines regulations and NMBI standards pertaining to prescription writing by the nurse or midwife prescriber include:

- *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations, 2007 (S.I. 201 of 2007)*
- *Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority (3rd Edition) (2018)*

In summary, these regulations require the prescription to:

- Be legible.
- State the full name of the person issuing it and include NMBI PIN.
- The prescription (including computer-generated prescriptions) must be in indelible ink.
- The prescription must be dated and signed by the nurse or midwife prescriber with her/his 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.
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:

- 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 2018) and Practice Notice 1/2010 (Pharmaceutical Society of Ireland, 2010) for further guidance regarding issuing prescriptions in an emergency.

3.1 Prescription Writing for Controlled Drugs

The Misuse of Drugs Regulations, 2017 states the particular requirements that must be met for a RNP 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 a RNP (Appendix II).
- The RNP 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 RNP must adhere to the Misuse of Drugs Regulations (2017) and the NMBI Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority 3rd Edition (NMBI, 2018) when prescribing MDA drugs.
- When prescribing MDA drugs, the RNP must ensure the prescription:
  - is in ink or otherwise so as to be indelible
  - clearly indicates the RNP’s full name, including the first name
  - states the NMBI PIN
  - is signed by him/her with his/her usual signature
  - is dated by him/her
  - specifies the RNP’s 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 RNP’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 RNP 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.
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.

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 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:
  - the name of the drug
  - dose
  - pharmaceutical form
  - strength (where appropriate)
  - 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.

3.2 Repeat Prescription Versus Instalment

The nurse or midwife prescriber 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 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

4.1 Prescribing for Off-Label Use

Off-label use refers to the use of an authorised medicinal product outside the terms of its Marketing Authority (MA). It is the prescribing of the medicinal product that is off-label, rather than the medicinal product itself. For example, a medicine authorised for adults only may be prescribed off-label in children.

- There is no impediment in the relevant legislation or professional regulation to a RNP prescribing a medicinal product for off-label use.
- The issuing of a prescription for a medicinal product, including off-label prescribing must be in accordance with Regulation 5A of the Medicinal Products (Prescription and Control of Supply) Regulations 2003, as amended.
- The Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority (NMBI 2018), Practice Standard 7, provides guidance on off-label prescribing by a RNP.
- The RNP should be knowledgeable in relation to best practice for prescribing a medicinal product for off-label use. This includes determining:
  - if there is an alternative authorised medicinal product that could be prescribed
  - if the medicinal product is regularly used to treat patients/service users in the RNP’s area of clinical practice
  - that the listing of the specific medicinal product is within the Health Service Providers’ prescribing guidelines (where such guidelines exist)
- The candidate/RNP in collaboration with the collaborating medical practitioner(s) should refer to the document Nurse and Midwife Medicinal Product Prescribing Toolkit: Authorised Medicinal Products, Off-label Prescription and Exempt Medicinal Products Toolkit (HPRA and HSE, 2017) for further support and information in the prescribing of medicinal products for off-label use.
- The HSE developed a form for the statutory and voluntary services of the HSE to assist in the decision making process for authorising a RNP to prescribe a medicinal product for off-label use (Appendix IV). This form must be submitted with the CPA for review by the D&T Committee or Review Group.

4.2 Exempt Medicinal Products

An Exempt Medicinal Product (EMP) is a medicinal product that is not authorised in Ireland by the HPRA 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 (Medicinal Products (Control of Placing on the Market) Regulations 2007) (Statutory Instruments No. 547 of 2007), as amended.

- The prescribing of EMPs by RNP is not provided for in the current medicinal products legislation and regulation and therefore must not be included on the CPA medicines listing.
- The RNP is legally and professionally accountable and responsible for their prescribing practices as mandated by the medicinal products legislation and the Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority (NMBI, 2018).
• A patient/service user’s requirement for a prescription for an EMP should be referred by the RNP to the appropriate registered medical practitioner.

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 RNP should ensure that prescription pads are stored in a secure place under lock and key when not in use
• The RNP should report promptly any loss or theft of prescription pads (or sections/pages of the prescription pads) to their line manager, relevant pharmacists, medical practitioners and, where applicable, Primary Care Reimbursement Services (PCRS) and complete and submit the relevant incident management form as per Health Service Provider policy
• The RNP, reporting the loss, should verify (where possible) the serial number and identify the number of unused prescription sheets remaining in the prescription pad
• The Director, or designated person, on behalf of the health service provider, should report any such incident to An Garda Síochána.

6.0 Adverse Reactions and Medication Errors/Near Misses

6.1 Adverse Reactions

RNPs should undertake to keep up to date with all prescribing information of the medicinal products they prescribe including up-to-date safety information. If an adverse drug reaction associated with the use of a medicine occurs during or following the administration of any medicinal preparation, the administration should cease immediately and the following steps should be taken:

• The RNP or nursing or midwifery staff should remain with the patient/service user and closely monitor for any adverse reactions
• Vital signs should be recorded
• 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 or midwifery and medical management and interventions must be recorded promptly
• The patient/service user (and/or family/carer where appropriate) should be informed of what has happened by the RNP or relevant nursing or midwifery and/or medical staff as per the National HSE Open Disclosure Policy (HSE, 2013)
• Where available, all vials, ampoules, infusions and remaining batches of medicinal preparations should be retained in accordance with local guidelines
• The RNP or relevant nursing or midwifery staff must report any suspected adverse reactions to relevant staff i.e. the pharmacy department/dispensing pharmacist and the clinical risk manager in line with local policy/guidelines
• The RNP or relevant nursing or 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 RNP or relevant nursing or midwifery staff may advise patients/service users that they can submit a report to the HPRA on any adverse drug 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 policy.

### 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 service users should be factually documented in the service user’s clinical/care record including details of the care provided and the salient points of the open disclosure discussion.

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 RNP 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)1837 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 policy
- The patient/service user (and family or carer where appropriate) must be informed of the incident as per National HSE Open Disclosure Policy (HSE, 2013)
- Any suspected adverse drug 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) as soon as is practicable 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. Services 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 fulfils 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). This includes the voluntary and statutory services of the HSE.

- RNPs are individually and professionally accountable to NMBI and their Health Service Provider employer 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
- 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 RNP 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 voluntary and statutory 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 RNPs to be issued with Primary Care Prescription Forms. The RNP’s GMS number will be allocated once the PCRS has been notified that the RNP is authorised by the Health Service Provider employer to commence prescribing.

- Specific criteria will apply to the decision to issue certain community RNPs with a Primary Care Prescription Pad
- In order to be issued with a Primary Care Prescription Pad, the RNP must complete The Application Form Notification and Authorisation of the Community Registered Nurse 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 policy 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.

The expectation for the HSE National Nurse and Midwife Medicinal Product Prescribing Policy (2018) is that healthcare professionals engaged in nurse and midwife medicinal product prescribing will use their clinical judgement and knowledge in implementing the content of this document.

1.1 Purpose
This national policy was originally developed and has been revised to continue to support a national standardised approach to nurse and midwife medicinal product prescribing in the voluntary and statutory services of the HSE.

1.2 Scope
This policy applies to:

- RNPs 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 register for nurse prescribers maintained by the NMBI
- Registered nurses and midwives employed in voluntary and statutory services of the HSE who are undertaking, or have undertaken an approved education programme in Nurse and Midwife Medicinal Product Prescribing, and/or are in the process of registering as a RNP with the NMBI
- All key stakeholders supporting nurse and midwife medicinal product prescribing in the HSE.

1.3 Aim and Objectives

1.3.1 Aim
The aim of this document is to provide a national standardised framework for nurse and midwife medicinal product prescribing reflecting current evidence based practice.

1.3.2 Objectives

- Provide a clinical governance framework with clear lines of responsibility and accountability to support nurse and midwife medicinal product prescribing
- Provide clear guidance, underpinned by legislation and regulation, to facilitate nurse and midwife medicinal product prescribing within health care settings
- Support the safety of patients/service users and staff
- Link nurse and midwife medicinal product prescribing to strategic service planning
- Support best practice with regard to nurse and midwife medicinal product prescribing
- Support health service providers who are participating in nurse and midwife medicinal product prescribing.
1.4 Outcomes
It is anticipated that this Policy will promote and enhance evidence based practice in nurse and midwife medicinal product prescribing in Ireland.

1.5 Policy 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 Policy Review Group and no conflicts of interest were noted (Appendix IX).

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

1.6 Policy Governance Group
The Director of the Office of Nursing and Midwifery Services and the National Director of Clinical Strategy and Programmes commissioned this revised Policy. The National Lead for nurse and midwife medicinal product prescribing (who reports to the Director of the Office of Nursing and Midwifery Services), managed, coordinated and administered the process. The Director of the ONMS views the implementation of this Policy at all levels of responsibility, as fundamental to the contribution of person centred care.

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 Policy

1.8 Glossary
See Appendix XI for a full glossary.

2.0 Policy Development

2.1 Policy Methodology
The evidence relating to nurse and midwife medicinal product prescribing was collected and critically appraised and used to update the exiting National Policy for Nurse and Midwife Medicinal Product Prescribing (HSE 2012).
2.2 Literature Search Strategy
A comprehensive literature search was undertaken which included a national and international literature review and peer review journals. The Policy Review Group (PRG) focused on updated Irish legislation, professional regulation and implementation documents to inform the revision of the Policy. Articles from 2012 – 2017 were prioritised, this being the time frame since the previous policy.

2.3 Evidence Appraisal
Evidence appraisal was not applicable for this Policy.

2.4 Grading of Recommendations
Grading of recommendations was not applicable for this Policy.

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 *Nurses and Midwives 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 or midwife prescriber, and the organisation (McBrien, 2015; Oxtoby, 2016; 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 collaborative approach, and through the provision of regular CPD days for RNPs, 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.

It has been identified in the UK that the introduction of nurse and midwife prescribing could potentially lead to confusion and conflict over role boundaries and definitions (Stenner et al, 2010). 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 2015. To clarify the level of autonomy at which nurses and midwives prescribe in Ireland, a CPA is required. This defines the parameters of the RNP’s scope of practice for prescriptive authority and provides clear lines of communication within the practice setting (NMBI, 2016). The Policy also clarifies the role and responsibilities of all stakeholders involved in nurse and midwife medicinal product prescribing.
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 recent 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.

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

Linked to this priority, the DoH Chief Nursing Officer (CNO) has identified two policy changes for nurses and midwives:

- Community nursing and midwifery response to an integrated model of care
- Developing a policy for graduate, specialist and advanced practice.

These policy changes support the development of the Registered Advanced Nurse Practitioner (RANP) role and also identify nurse and midwife medicinal product prescribing as a critical component for service delivery.

The HSE Service Plans have identified increasing capacity of RNPs as a priority within the nursing and midwifery services (HSE, 2017, 2018).

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.
This Policy also supports the Health Information Quality Authority *National Standards for Safer Better Healthcare* (2012)

Standard 5.1:

“Service providers have clear accountability arrangements to achieve the delivery of high quality, safe and reliable health”. The standard states “A key function of governance is specifying the accountability and reporting structures in the service at individual, team and service level so that everyone working in the service is aware of their responsibility and accountability for the delivery of high quality, safe and reliable care”.

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 the access to medicines and the timeliness of interventions for those seeking treatment.

2.6 Resources

A budget impact analysis was not undertaken. This revised Policy (2018) is a revision of the National Policy for Nurse and Midwife Medicinal Product Prescribing published in 2012. The Policy 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 Policy Steps

Refer to Part A for the details of this Policy.

3.0 Governance and Approval

3.1 Governance

The sponsors of this Policy review, the Director of the Office of Nursing and Midwifery Services and the National Director of Clinical Strategy and Programmes have the authority and responsibility for managing and executing this review and revision. The PRG worked with all resources to revise the Policy.

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

The revised National Policy was reviewed to ensure compliance with *The Policies, Procedures, Protocols and Guidelines Checklist for Developing Clinical PPPGs* (2016) (Appendix XII).

3.2.1 National Stakeholder and Expert Review

Once the draft Policy received approval from the PRG, consultation was undertaken with relevant national stakeholders and experts to ensure consensus on the revised Policy. It was circulated to relevant organisations for comments between October and November 2017. Stakeholders were asked to comment on the Policy and submit feedback with supporting evidence on a form provided. A timeframe of two weeks was allocated to submit comments. All feedback received was reviewed by the PRG.

Suggested amendments and supporting evidence were reviewed by the PRG and consensus reached to accept or reject the amendments. All modifications were documented.
3.3 **Copyright/Permission Sought**
No copyright or permissions were required for the revision of this Policy.

3.4 **Approval and Sign Off**
The final draft of the revised *HSE National Policy for Nurse and Midwife Medicinal Product Prescribing* (2018) was submitted for approval, accompanied by the signed PPPG Checklist (Appendix XII) confirming that all stages in the revision of the Policy 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 Office of Nursing and Midwifery Services and the National Director of Clinical Strategy and Programmes Division HSE.

4.0 **Communication and Dissemination**
It is important that the Policy is disseminated as soon as it has been completed. This approach will ensure that this Policy can be implemented immediately to support candidates, RNPs and Health Service Providers involved in nurse and midwife medicinal product prescribing.

This national Policy will be widely communicated and disseminated to all relevant stakeholders. The following activities will be undertaken:

- All relevant stakeholders to receive a copy of the policy
- Upload the policy to relevant webpage ([www.hse.ie/go/nurseprescribing](http://www.hse.ie/go/nurseprescribing))
- Liaise with PSCs in all health service providers for on-going dissemination
- Disseminate through the ONMSD HSE communication channels
- Circulate via the RNP and PSC eNetworks.

5.0 **Implementation**

5.1 **Implementation of the Policy**
Implementation of the Policy will follow dissemination and communication.

5.2 **Barriers and Facilitators to Implementation**
There are no barriers that will impact on the full implementation of this revised Policy. The implementation of the Policy can be facilitated by ensuring that all healthcare professionals understand and appreciate that the Policy contributes to the quality and safety of patient care.

5.3 **Education**
Education sessions will be provided on publication of this Policy if required.

5.4 **Responsibility for Implementation**
All stakeholders involved in nurse and midwife medicinal product prescribing have a responsibility for the implementation of this Policy. Refer to Part A for detailed responsibilities for individual stakeholders.

5.5 **Health Service Provider Responsibility**
Each General Manager, Chief Executive Officer, Chief Officer, The Director of Nursing/Midwifery and the Clinical Director of the Health Service Provider have corporate responsibility for the implementation of this Policy. Each member of the multidisciplinary team is responsible for the implementation of the Policy relevant to their discipline.
5.6 Roles and Responsibilities

Senior Managers:
- Support the implementation of the Policy
- Assign personnel with responsibility, accountability and autonomy to implement the Policy
- Provide managers with support to implement the Policy
- Ensure local policies and procedures are in place to support implementation
- Ensure clinical and educational staff are supported to implement the Policy
- Monitor the implementation of the Policy
- Ensure audit programmes for prescribing practices are in place.

Heads of Department:
- Ensure all relevant staff members are aware of this Policy and supporting policies and PPPGs
- Ensure staff are supported to undertake education programmes and related training, as appropriate.

Clinical Staff:
- Clinical staff should comply with this Policy and related PPPGs. A copy of the signature sheet should be signed to show all relevant staff have read, understand and agree to adhere to this Policy (Appendix XIII).

6.0 Monitoring, Audit and Evaluation

6.1 The Plan
Audit of nurse and midwife medicinal product prescribing is essential to support best practice in the delivery and evaluation of their practice. It is a requirement of the NMBI and the HSE that each Health Service Provider has a mechanism in place to review and audit prescribing practices of RNPs as part of its overall organisational audit programme for prescribing and medicines management. It is recommended that the audit process is coordinated locally by each Health Service Provider. The audit process should be undertaken from a multidisciplinary perspective where appropriate. Please refer to the publication *Nurse and Midwife Medicinal Product Prescribing Toolkit: Guidance for Clinical Audit* (HSE, 2016)

6.1.1 Monitoring
It is recommended that Health Service Providers should undertake monitoring and audit regularly to support the implementation and monitoring of nurse and midwife medicinal product prescribing locally, as part of the continuous quality improvement cycle. It is important that feedback is given to the relevant staff groups to ensure appropriate action plans are implemented.

*The Nurse Midwife Prescribing Data Collection System* is a monitoring system specifically developed to support nurse and midwife medicinal product prescribing. While use of the System is not mandatory the search and reporting facilities can be used to support individual monitoring for those who choose to use this system. To support services wishing to avail of the monitoring and reporting facility of the System, it is available at [https://www.nurseprescribing.ie](https://www.nurseprescribing.ie).
6.1.2 Audit
The Health Service Provider, in collaboration with the RNP, will agree and define the criteria for audit including; mechanism, personnel involved, frequency and the reporting requirements. Supporting audit guidance and tools are available at https://www.nurseprescribing.ie.

There is a requirement in the CPA to outline the process for review and audit of RNPs’ prescriptive practices.

6.1.3 Evaluation
The audit cycle is a continuous process. Quality improvement plans are put in place and evaluation should be performed to ensure plans are implemented as agreed, and within the agreed timeframe. The Health Service Provider should identify those responsible for monitoring and evaluating the quality improvement plan.

7.0 Revision/Update

7.1 Procedure for Revising the Policy
The PRG has agreed that this Policy will be reviewed on a 3-yearly basis and updated as appropriate. Therefore, this Policy will be reviewed in 2021. An updated systematic literature search will be undertaken at that time and the Policy 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 policy will maintain its relevance and currency. Any updates/addendums to the policy in the interim period or as a result of the three year review will be subject to approval.

7.3 Version Control
The original National Policy for Nurse and Midwife Medicinal Product Prescribing was issued in 2012. This Policy replaces the 2012 version. The revised Policy will be available on the HSE website. This is a controlled policy and will be available electronically at www.hse.ie/go/nurseprescribing
8.0 References


Health Service Executive (2012). *Quality and Patient Safety, Clinical Governance Development* (An assurance check for health service providers) Dublin: Health Service Executive


Health Service Executive National Incident Management Team (2014). *Safety Incident Management Policy* Dublin: Health Service Executive

Health Service Executive (2014). *Nurse and Midwife Medicinal Product Prescribing Toolkit Introduction and Background* Dublin: Health Service Executive

Health Service Executive and Nursing and Midwifery Board of Ireland (2015). *Report on Nurse and Midwife Medicinal Product Prescribing Review of Existing Systems and Processes* Dublin: Nursing and Board of Ireland


Health Service Executive and Nursing and Midwifery Board of Ireland (2017). *Nurse and Midwife Medicinal Product Prescribing Toolkit: Drugs and Therapeutics Committee* Dublin: Health Service Executive


Health Service Executive (2018). *Nurse and Midwife Medicinal Product Prescribing Toolkit Cross Site(s) Prescribing/Integrated Role* Dublin: Health Service Executive


Nursing and Midwifery Board of Ireland (2014). *The Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives*. Dublin: Nursing and Midwifery Board of Ireland

Nursing and Midwifery Board of Ireland (2015). *Prescriptive Authority for Nurses and Midwives: Standards and Requirements* Dublin: Nursing and Midwifery Board of Ireland

Nursing and Midwifery Board of Ireland (2015). *Recording Clinical Practice Guidance to Nurses and Midwives*. Dublin: Nursing and Midwifery Board of Ireland

Nursing and Midwifery Board of Ireland (2015). *Scope of Nursing and Midwifery Practice Framework*. Dublin: Nursing and Midwifery Board of Ireland

Nursing and Midwifery Board of Ireland (2016). *Collaborative Practice Agreement Guidance for Nurses and Midwives with Prescriptive Authority. 4th Edition*. Dublin: Nursing and Midwifery Board of Ireland

Nursing and Midwifery Board of Ireland (2018). *Practice Standards for Midwives (3rd Edn)*. Dublin: Nursing and Midwifery Board of Ireland


## Appendix I: Principles for Clinical Governance Development

<table>
<thead>
<tr>
<th>Principle</th>
<th>Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient First</td>
<td>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.</td>
</tr>
<tr>
<td>Safety</td>
<td>Identification and control of risks to achieve effective efficient and positive outcomes for patients and staff.</td>
</tr>
<tr>
<td>Personal Responsibility</td>
<td>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.</td>
</tr>
<tr>
<td>Defined Authority</td>
<td>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.</td>
</tr>
<tr>
<td>Clear Accountability</td>
<td>A system whereby individuals, functions or committees agree accountability to a single individual.</td>
</tr>
<tr>
<td>Leadership</td>
<td>Motivating people towards a common goal and driving sustainable change to ensure safe high quality delivery of clinical and social care.</td>
</tr>
<tr>
<td>Inter-Disciplinary Working</td>
<td>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.</td>
</tr>
<tr>
<td>Supporting Performance</td>
<td>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).</td>
</tr>
<tr>
<td>Open Culture</td>
<td>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.</td>
</tr>
<tr>
<td>Continuous Quality Improvement</td>
<td>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</td>
</tr>
</tbody>
</table>
Appendix II: 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**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Route of Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buprenorphine</td>
<td>Transdermal</td>
</tr>
<tr>
<td>Codeine Phosphate</td>
<td>Oral</td>
</tr>
<tr>
<td>Dihydrocodeine</td>
<td>Oral</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>Intranasal, intravenous, transdermal, transmucosal, subcutaneous, sublingual/buccal</td>
</tr>
<tr>
<td>Morphine Sulphate</td>
<td>Intramuscular, intravenous, oral, subcutaneous</td>
</tr>
<tr>
<td>Morphine Tartrate</td>
<td>Intramuscular, intravenous, subcutaneous</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>Oral, subcutaneous, intravenous</td>
</tr>
<tr>
<td>Pethidine</td>
<td>Intramuscular, intravenous, subcutaneous</td>
</tr>
</tbody>
</table>

**PART 2**

**Drugs for Palliative Care**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Route of Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buprenorphine</td>
<td>Transdermal</td>
</tr>
<tr>
<td>Codeine Phosphate</td>
<td>Oral</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>Intranasal, intravenous, transdermal, transmucosal, subcutaneous, sublingual/buccal</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>Oral, subcutaneous</td>
</tr>
<tr>
<td>Methylphenidate</td>
<td>Oral</td>
</tr>
<tr>
<td>Morphine Sulphate</td>
<td>Intramuscular, oral, subcutaneous</td>
</tr>
<tr>
<td>Morphine Tartrate</td>
<td>Intramuscular, subcutaneous</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>Oral, subcutaneous, intravenous</td>
</tr>
</tbody>
</table>

**PART 3**

**Drugs for Purposes of Midwifery**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Route of Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pethidine</td>
<td>Intramuscular</td>
</tr>
</tbody>
</table>

**PART 4**

**Drugs for Neonatal Care**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Route of Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fentanyl</td>
<td>Intravenous, transdermal, transmucosal</td>
</tr>
<tr>
<td>Morphine Sulphate</td>
<td>Intramuscular, intranasal, intravenous, oral, subcutaneous</td>
</tr>
<tr>
<td>Morphine Tartrate</td>
<td>Intramuscular, intravenous, subcutaneous</td>
</tr>
</tbody>
</table>

**PART 5**

**Drugs for Use in Mental Health or Intellectual Disability**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Route of administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methylphenidate</td>
<td>Oral</td>
</tr>
</tbody>
</table>
**Appendix III: Sample Commencement Letter**

Date [insert details]

Registered Nurse Prescriber’s Name [insert details]
Clinical Grade [insert details]
Ward/Unit/Organisation [insert details]
Address 1
Address 2
Address 3

**Re: Commencement Date for Nurse Medicinal Product Prescribing at [insert name of Health Service Provider]**

Dear [insert details]

Congratulations on registering with Nursing and Midwifery Board of Ireland as a Registered Nurse 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 as documented in the Collaborative Practice Agreement (CPA) signed on [insert date]. Please also ensure that your practice is in compliance with the relevant legislation, professional guidance and regulations in particular the following:

- HSE Nurse and Midwife Medicinal Product Prescribing Policy (2018)
- Nursing and Midwifery Board of Ireland (2018) Practice Standards and Guidelines for Nurse and Midwives with Prescriptive Authority.
- Nursing and Midwifery Board of Ireland (2016) Collaborative Practice Agreement for Nurses and Midwives with Prescriptive Authority (Fourth edition).
- Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007
- Misuse of Drugs Regulations 2017

As a Registered Nurse Prescriber you are responsible for maintaining continued competence and auditing your practice in accordance with our organisations and the Nursing and Midwifery Board of Ireland requirements. To assist you in this the [Nurse and Midwife Prescribing Data Collection System](https://www.nurseprescribing.ie) is available for you at [https://www.nurseprescribing.ie](https://www.nurseprescribing.ie).

In order to support nurse and midwife prescribers the [Office of the Nursing and Midwifery Service Director](https://www.onsd.ie) (ONMSD), has established the following:

- An email communication mechanism called the [Irish-RNP-eNetwork](https://www.nurseprescribing.ie)
- The [Journal of Nurse Prescribing](https://www.nurseprescribing.ie) (full text articles) available to you through the ‘resources’ section of the [Nurse and Midwife Prescribing Data Collection System](https://www.nurseprescribing.ie). When you go to this section, you will need the following username and password:
  - Username: nursing.services@hse.ie
  - Password: internurse189
- The Nurse and Midwife Medicinal Product Prescribing Website -
  http://www.hse.ie/go/nurseprescribing

It is important for all RNPs to keep up to date with prescribing information of the medicinal products they prescribe 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 competencies within your clinical area of practice.

With Kind Regards

Yours Sincerely

Director of Nursing
Appendix IV: Nurse Midwife Medicinal Product Prescribing Form.

Governance Process for Health Service Providers to Authorise Registered Nurse Prescribers (RNPs) to Prescribe Medicinal Products for Off-Label Use

Section 1: To Be Completed by the Candidate/RNP

<table>
<thead>
<tr>
<th></th>
<th>Name of Candidate/RNP (as per NMBI) NMBI Personal Identification Number (PIN)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Clinical Area(s) of Practice</td>
</tr>
<tr>
<td>3</td>
<td>Name of Medicinal Product</td>
</tr>
<tr>
<td>4</td>
<td>Dose, Route, Form</td>
</tr>
<tr>
<td>5</td>
<td>Clinical indication for off-label prescribing of this medicinal product</td>
</tr>
<tr>
<td>6</td>
<td>Rationale for inclusion of this off-label medicinal product on my Collaborative Practice Agreement (CPA) (Evidence base must be included/attached)</td>
</tr>
<tr>
<td>7</td>
<td>Is this medicinal product regularly used to treat patients/service users in this clinical area(s) of practice?</td>
</tr>
<tr>
<td>8</td>
<td>Is this medicinal product included in the Health Service Providers’ prescribing guidelines (where such guidelines exist)?</td>
</tr>
<tr>
<td>9</td>
<td>Is there an alternative authorised medicinal product that could be prescribed?</td>
</tr>
<tr>
<td></td>
<td>If the answer is “YES” the Candidate/RNP must not submit this form for authorisation</td>
</tr>
<tr>
<td>10</td>
<td>Is this an investigational medicinal product, intended for use in the context of a clinical trial?</td>
</tr>
<tr>
<td></td>
<td>If the answer is “YES” the Candidate/RNP must not submit this form for authorisation</td>
</tr>
</tbody>
</table>

Signature of Candidate/RNP

Date
Section 2: To be completed by the Collaborating Medical Practitioner/s
I have discussed this with the candidate/RNP and I support the inclusion of the above medicinal product for off-label use (ordinarily used in the clinical setting) on the CPA.

Signature of Collaborating Medical Practitioner: __________________________________________
Date:       __________________________________________

Signature of Collaborating Medical Practitioner: __________________________________________
Date:       __________________________________________

Signature of Collaborating Medical Practitioner: __________________________________________
Date:       __________________________________________

Section 3: To be completed by the Drugs and Therapeutics Committee/Review Group

<table>
<thead>
<tr>
<th></th>
<th>Name of Medicinal Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>The medicinal product is regularly used to treat patients/service users in the candidate/RNPs clinical area of practice?</td>
</tr>
</tbody>
</table>

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>The medicinal product is included in the health service providers' prescribing guidelines (where such guidelines exist)</td>
</tr>
</tbody>
</table>

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Is this medicinal product authorised for use in any European country or other international country? (please specify the country and authorising authority)</td>
</tr>
</tbody>
</table>

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>There is no alternative medicinal product that could be prescribed?</td>
</tr>
</tbody>
</table>

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>The use of this medicinal product is not in the context of a clinical trial?</td>
</tr>
</tbody>
</table>

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>Is the committee satisfied with the prescribing information, safety profile and appropriateness of the proposed clinical indications for the off-label prescribing of the medicinal product?</td>
</tr>
</tbody>
</table>

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>Is there a clear rationale and evidence base for this medicinal product to be prescribed by this RNP?</td>
</tr>
</tbody>
</table>

The Committee/Review Group has reviewed and considered the information supplied and supports the inclusion of the medicinal product for off-label use on the RNP’s CPA.

Signature of Chair of Drugs and Therapeutics Committee/Review Group

__________________________________________________________________________________

Signature of Candidate/RNP: ________________________________________________________
Date:    ________________________________________________________
Section 4: Approval

This Candidate/RNP is approved to include this medicinal product for off-label use on their CPA and when registered as a RNP is authorised to prescribe this medicinal product off-label within their scope of practice and the Health Service Provider’s prescribing policy.

Name of Medicinal Product: ________________________________

Name of Candidate/RNP: ________________________________

Clinical Area of Practice: ________________________________

Signature of Director of Nursing/Midwifery/Public Health Nursing/Services Manager or Authorised Representative of the Health Service Provider

Name: _________________________________________________

Title: _________________________________________________

Date: _________________________________________________
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 practising 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 by RNPs

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 RNPs

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

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

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

Part 1: Registered Nurse Prescriber to Complete

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

<table>
<thead>
<tr>
<th></th>
<th>Insert Details/Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>RNP name (use block capitals)</td>
</tr>
<tr>
<td></td>
<td>▪ Forename</td>
</tr>
<tr>
<td></td>
<td>▪ Surname</td>
</tr>
<tr>
<td>2</td>
<td>An Bord Altranais Personal Identification Number (PIN)</td>
</tr>
<tr>
<td>3</td>
<td>Date registered as an RNP with An Bord Altranais</td>
</tr>
<tr>
<td>4</td>
<td>HSE Health Area Manager/Local Health Office (LHO) Area of Employment and Health Area/LHO Number</td>
</tr>
<tr>
<td>5</td>
<td>HSE Statutory/Voluntary Services Employee Number (i.e. personnel number)</td>
</tr>
<tr>
<td>6</td>
<td>Contact address of HSE Statutory/Voluntary HSE service where I am employed and from which authorised to prescribe</td>
</tr>
<tr>
<td>7</td>
<td>Contact details</td>
</tr>
<tr>
<td></td>
<td>▪ Office telephone inc pre-fix</td>
</tr>
<tr>
<td></td>
<td>▪ Mobile</td>
</tr>
<tr>
<td></td>
<td>▪ email</td>
</tr>
</tbody>
</table>
8. My clinical area of practice is (for example public health nursing, tissue viability, palliative care etc.)

9. Name of Collaborating General Practitioner(s) (if multiple please insert names or attach list)

10. My CPA was authorised (give date)  

    D D M M Y Y Y Y

11. I commit to regular audit of my prescribing practice in accordance with An Bord Altranais Practice Standards and Guidance for Nurses and Midwives with Prescriptive Authority (2010) and the Policy for Medicinal Product Prescribing for my service area.

[ Tick box to confirm ]

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:

[ Signature ]  Date:  

DDMMYYYY

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

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

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

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

Signature of Director:

[ Signature ]  Date:  

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

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

Signature of HSE Health Area Manager/LHO Manager:

<table>
<thead>
<tr>
<th>LHO No:</th>
<th>Date:</th>
<th>D</th>
<th>D</th>
<th>M</th>
<th>M</th>
<th>Y</th>
<th>Y</th>
<th>Y</th>
<th>Y</th>
<th>Y</th>
</tr>
</thead>
</table>

Part 4: PCRS to complete (for internal use)

<table>
<thead>
<tr>
<th>Action</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1 HSE Health Area/LHO Number</td>
<td></td>
</tr>
<tr>
<td>2 GMS Number assigned</td>
<td></td>
</tr>
<tr>
<td>3 Date issued</td>
<td></td>
</tr>
<tr>
<td>4 Details entered</td>
<td></td>
</tr>
<tr>
<td>5 PCRS Officer</td>
<td></td>
</tr>
</tbody>
</table>
Appendix VIII: Membership of the Policy Review Group

1. Policy Review Group Members

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clare Mac Gabhann</td>
<td>National Lead, Director of Nursing and Midwifery (Prescribing)</td>
</tr>
<tr>
<td>Annette Cuddy</td>
<td>Assistant Director of Nursing and Midwifery (Prescribing)</td>
</tr>
<tr>
<td>Maureen Nolan</td>
<td>Director of Nursing, National Lead for the Implementation and Audit of Nurse Prescribing of Ionising Radiation</td>
</tr>
<tr>
<td>Rose Lorenz</td>
<td>Assistant Director of Nursing and Midwifery (Prescribing)</td>
</tr>
<tr>
<td>Lorraine Barensther</td>
<td>Clerical Officer</td>
</tr>
</tbody>
</table>
Appendix IX: Conflict of Interest Declaration Form

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 Policy

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.

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Áine Carroll</td>
<td></td>
<td>31/5/18</td>
</tr>
<tr>
<td>National Director of Clinical Strategy and</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Programmes, HSE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MS Mary Wynne</td>
<td>Mary Wynne</td>
<td>18th May 2018</td>
</tr>
<tr>
<td>Interim Nursing and Midwifery Services Director, HSE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chairperson:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clare Mac Gabhann</td>
<td></td>
<td>17th May 2018</td>
</tr>
<tr>
<td>National Lead, Director of Nursing and</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Midwifery (Prescribing), HSE</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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 by the HPRA to be marketed in Ireland, or by the European Commission (following a common EU assessment procedure coordinated 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 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 whose name is entered on the Candidate Register of An Bord Altranais and is undertaking an approved programme of education and training leading to registration in the registered nurse prescribers division of the register or a nurse or midwife who has successfully completed the approved educational programme and is in the process of registering with 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 medicinal products and off-label prescribing providing the latter is used with the expressed knowledge and consent of the enterprises management.

- **Collaborating Medical Practitioner(s)**: The medical practitioner or group of medical practitioners with whom the RNP has a written collaborative practice agreement as part of the requirements to prescribe medicinal products within his/her scope of practice.

- **Collaborative Practice Agreement (CPA)**: The CPA is drawn up with the agreement of the Candidate/RNP, the Collaborating Medical Practitioner(s) and the Director of Nursing/Midwifery/Public Health Nursing/Service Manager on behalf of the Health Service Provider outlining the parameters of the RNP’s prescribing authority (i.e. their scope of practice). The principles of professional accountability, responsibility, competence and clinical governance underpin the CPA (NMBI, 2017).
• **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 optimal 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, including RNPs. It is strongly recommended that each Health Service Provider has a D&T Committee in place, or has access to one. In the absence of a D&T Committee, a Review Group may be established with specific terms of reference for nurse and midwife medicinal product prescribing. This Committee or Review Group must include at a minimum, representation from senior nursing and midwifery personnel (Director of Nursing/Midwifery/PHN; Nurse/Midwife Practice Development Coordinator), medical personnel (GP/Consultant), and pharmacy personnel.

• **Exempt Medicinal Product (EMP):** An EMP is a medicinal product that is **not authorised in Ireland**, by the HPRA but which can legally be 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 (*Medicinal Products (Control of Placing on the Market) Regulations 2007* (S.I. No. 540 of 2007), as amended). The term exempt refers to the fact that such products are exempt from the legal requirement to hold a Marketing Authorisation, on condition that their supply is in line with the above requirements.

• **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 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 Immunoglobin 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.

• **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 which could have resulted in harm but did not, either by chance or timely intervention. (An Bord Altranais, 2007).
• **Off-label Use:** Off-label use refers to the use of an authorised medicinal product outside the terms of its marketing authorisation. It is the prescribing of the medicinal product that is off-label, rather than the medicinal product itself.

• **Open Disclosure:** An open, consistent approach to communicating with service users when things go wrong in healthcare. This includes expressing regret for what has happened, keeping the service user informed, providing feedback on investigations and the steps taken to prevent a recurrence of the adverse event.

• **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 license to market a medicinal product granted by the Health Products Regulatory Authority (formerly Irish Medicines Board) in accordance with Article 7 of the Medicinal Products (Licensing and Sale Regulations, 1998).

• **Primary Care Reimbursement Service (PCRS):** The PCRS is part of the HSE. PCRS supports the delivery of primary healthcare by providing reimbursement services to primary care contractors for the provision of health services to members of the public in their own community. PCRS is responsible for making payments to healthcare professionals, e.g. doctors, dentists and pharmacists, for the free or reduced costs services they provide to the public.

• **Registered Nurse Prescriber (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). ‘RNP’ is used throughout this document to include nurse and midwife manager as this is the current legal description of a registered nurse or midwife with prescriptive authority.

• **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 SmPC forms the basis of prescribing information for healthcare professionals. Within the EU, the SmPC forms part of the authorisation that a company must acquire for any medicine it wishes to market. In Ireland, the SmPC for each authorised product are accessible from [http://www.hpra.ie](http://www.hpra.ie)
Appendix XII: Approved Policies, Procedures, Protocols and Guidelines Checklist

<table>
<thead>
<tr>
<th>Standards for Developing Clinical PPPG</th>
<th>Checklist</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stage 1 Initiation</strong></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td>✓</td>
</tr>
<tr>
<td>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.</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Title: National Nurse and Midwife Medicinal Product Prescribing Policy 2018</strong></td>
<td></td>
</tr>
<tr>
<td>The scope of the PPPG is clearly described, specifying what is included and what lies outside the scope of the PPPG.</td>
<td>✓</td>
</tr>
<tr>
<td>The target users and the population/patient group to whom the PPPG is meant to apply are specifically described.</td>
<td>✓</td>
</tr>
<tr>
<td>The views and preferences of the target population have been sought and taken into consideration (as required).</td>
<td>✓</td>
</tr>
<tr>
<td>The overall objective(s) of the PPPGs are specifically described.</td>
<td>✓</td>
</tr>
<tr>
<td>The potential for improved health is described (e.g. clinical effectiveness, patient safety, quality improvement, health outcomes, quality of life, quality of care).</td>
<td>✓</td>
</tr>
<tr>
<td>Stakeholder identification and involvement: The PPPG Development Group includes individuals from all relevant stakeholders, staff and professional groups.</td>
<td>✓</td>
</tr>
<tr>
<td>Conflict of interest statements from all members of the PPPG Development Group are documented, with a description of mitigating actions if relevant.</td>
<td>✓</td>
</tr>
</tbody>
</table>
The PPPG is informed by the identified needs and priorities of service users and stakeholders. | √
---|---
There is service user/lay representation on PPPG Development Group (as required). | √
---|---
Information and support is available for staff on the development of evidence-based clinical practice guidance. | √
---|---

<table>
<thead>
<tr>
<th>Stage 2 Development</th>
<th>Checklist</th>
</tr>
</thead>
<tbody>
<tr>
<td>The clinical question(s) covered by the PPPG are specifically described.</td>
<td>√</td>
</tr>
<tr>
<td>Systematic methods used to search for evidence are documented (for PPPGs which are adapted/adopted form international guidance, their methodology is appraised and documented).</td>
<td>√</td>
</tr>
<tr>
<td>Critical appraisal/analysis of evidence using validated tools is documented (the strengths, limitations and methodological quality of the body of evidence are clearly described).</td>
<td>√</td>
</tr>
<tr>
<td>The health benefits, side effects and risks have been considered and documented in formulating the PPPG.</td>
<td>√</td>
</tr>
<tr>
<td>There is an explicit link between the PPPG and the supporting evidence.</td>
<td>√</td>
</tr>
<tr>
<td>PPPG guidance/recommendations are specific and unambiguous.</td>
<td>√</td>
</tr>
<tr>
<td>The potential resource implications of developing and implementing the PPPG are identified e.g. equipment, education/training, staff time and research.</td>
<td>√</td>
</tr>
<tr>
<td>There is collaboration across all stakeholders in the planning and implementation phases to optimise patient flow and integrated care.</td>
<td>√</td>
</tr>
<tr>
<td>Requirement</td>
<td>Status</td>
</tr>
<tr>
<td>----------------------------------------------------------------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>Budget impact is documented (resources required).</td>
<td>√</td>
</tr>
<tr>
<td>Education and training is provided for staff on the development and implementation of evidence-based clinical practice guidance (as appropriate).</td>
<td>√</td>
</tr>
<tr>
<td>Three additional standards are applicable for a small number of more complex PPPGs:</td>
<td>Not deemed necessary</td>
</tr>
<tr>
<td>Cost effectiveness analysis is documented.</td>
<td></td>
</tr>
<tr>
<td>A systematic literature review has been undertaken.</td>
<td>√</td>
</tr>
<tr>
<td>Health Technology Assessment (HTA) has been undertaken.</td>
<td>Not undertaken</td>
</tr>
</tbody>
</table>

### Stage 3 Governance and Approval Checklist

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formal governance arrangements for PPPGs at local, regional and national level are established and documented.</td>
<td>√</td>
</tr>
<tr>
<td>The PPPG has been reviewed by the independent experts prior to publication (as required).</td>
<td>√</td>
</tr>
<tr>
<td>Copyright and permissions are sought and documented.</td>
<td>√</td>
</tr>
</tbody>
</table>

### Stage 4 Communication and Dissemination Checklist

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>A communication plan is developed to ensure effective communication and collaboration with all stakeholders throughout all stages.</td>
<td>√</td>
</tr>
<tr>
<td>Plan and procedure for dissemination of the PPPG is described.</td>
<td>√</td>
</tr>
<tr>
<td>The PPPG is easily accessible by all users e.g. PPPG repository.</td>
<td>√</td>
</tr>
</tbody>
</table>

### Stage 5 Implementation Checklist

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Written implementation plan is provided with timelines, identification of responsible persons/units and integration into service planning process.</td>
<td>√</td>
</tr>
</tbody>
</table>
Barriers and facilitators for implementation are identified, and aligned with implementation levers.  

Education and training is provided for staff on the development and implementation of evidence-based PPPG (as required).  

There is collaboration across all stakeholders in the planning and implementation phases to optimise patient flow and integrated care.

<table>
<thead>
<tr>
<th>Stage 6 Monitoring, Audit, Evaluation</th>
<th>Checklist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Process for monitoring and continuous improvement is documented</td>
<td>✔</td>
</tr>
<tr>
<td>Audit criteria and audit process/plan are specified</td>
<td>✔</td>
</tr>
<tr>
<td>Process for evaluation of implementation and (clinical) effectiveness is specified</td>
<td>✔</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Stage 7 Revision/Update</th>
<th>Checklist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Documented process for revisions/updating and review, including timeframe is provided</td>
<td>✔</td>
</tr>
<tr>
<td>Documented process for version control is provided</td>
<td>✔</td>
</tr>
</tbody>
</table>

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

**Title of PPPG: HSE National Nurse and Midwife Medicinal Product Prescribing 2018**

**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.
Appendix XIII: Signature Sheet

Signature Sheet

I have read, understand and agree to adhere to this Policy:

<table>
<thead>
<tr>
<th>Print Name</th>
<th>Signature</th>
<th>Area of Work</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
