

HSCB and PHA Process for Developing Prescribing Guidance and Formulary Chapters

March 2016

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1. Background

1.1. The DHSSPS requested in Priorities for Action 2010/11, that the HSCB establish a formulary. Following public consultation on the process to develop the formulary, which reported to Board in November 2011, the HSCB has taken the development work forward. To date, ten chapters of the formulary have now been approved, covering approximately 90% of prescribing choices. Whilst the formulary will aim to standardise practice and ensure a level of consistency, it is recognised that individual patients may require medicines which lie outside such guidance.

1.2. Moving forward, the formulary will require regular review and update to ensure that it remains relevant to and supportive of contemporary prescribing practice.

1.3. In addition to the Northern Ireland Formulary, there is occasionally a requirement to produce pieces of prescribing guidance which are identified via a number of sources:

- Pharmaceutical Clinical Effectiveness (PCE) Programme – annual programme which identifies main areas for therapeutic review/guideline consideration
- Safety/quality issues
- Ad hoc, e.g. a request from primary or secondary care clinicians due to increased referral rates/inappropriate referral rates
- Where a National Institute for Health and Care Excellence (NICE) Technology Appraisal or Guideline exists, and has been approved for use in Northern Ireland, it is assumed that local guidance will not be needed. However, where a NICE Single Technology Appraisal is issued there may occasionally be a requirement to clarify how this guidance sits relative to other prescribing choices.

The process described within this paper will be used to develop substantive pieces of prescribing guidance.

The Medicines Management Commissioning Team (MMCT) will determine the need for substantive guidance.

1.4. In December 2012, NICE published the Good Practice Guidance - "Developing and updating local formularies".

NICE made recommendations in each of the following areas with respect to developing formularies:

- Relations with other decision making bodies
- Formulary scope
- Local formulary decision making group
- Stakeholder engagement
- Process for selecting medicines to be considered
- Adoption of NICE Technology Appraisal recommendations
- Setting decision criteria
- Evidence and information gathering
- Incorporating new evidence from regulatory authorities
- Assessment of financial and commissioning impact
- Deliberating and reaching decisions
- Documentation
- Decision outputs
- Communication and dissemination
- Reconsideration and appeals of decisions
- Reviewing and updating

The Northern Ireland Formulary Process Document from November 2011 was reviewed against NICE good practice guidance 'Developing and updating local formularies' and revisions were made. However, it should be noted that this guideline is written in the context of the NHS in England. The scope of the NI Formulary is to provide advice on first and second choice medicines. The scope of local formularies in England is broader and therefore some recommendations are not applicable to the NI Formulary.

2.1. This process will be applied when developing the formulary and any other substantive clinical prescribing guidance across primary and secondary care. The decision to commission the development of clinical prescribing guidance in line with this process will be undertaken by MMCT. It is anticipated that less substantive advice/guidance will not be required to follow the entire process as set out and this will be informed by the range of professional

advice within MMCT. Typically, the NI Formulary website will be the repository for HSCB prescribing guidance.

- 2.2. The scope of the NI Formulary is to provide all prescribers with guidance on first and second choice medicines (where appropriate). The scope of other prescribing guidance may be much broader than first and second line treatments. The selection of medicines in both the formulary and prescribing guidance is based on clinical *effectiveness, safety, cost effectiveness and patient acceptability*, taking into account NICE and other national guidance where appropriate.
- 2.3. The NI Formulary and prescribing guidance which falls within this process are intended to be used across both primary and secondary care sectors in NI to facilitate consistency of prescribing and continuity of supply. However, it is recognised that within the secondary care sector, first and second line choices may already have been prescribed and therefore compliance rates with the formulary in secondary care may not match the compliance rates expected in primary care.
- 2.4. The medicines that will be included in the formulary will be sufficient to meet the needs of the majority of patients (70%) but clearly not all. Prescribing guidance is usually focussed at particular therapeutic areas and covers such areas in greater depth such that more than 70% of prescribing choices for that therapeutic area will be covered. The remit of both the formulary and prescribing guidance recognises that individual patients may require medicines outside of the recommended first line choices or treatments and therefore it will not cover 100% of all prescribing.
- 2.5. In proposing the development and review of individual formulary chapters and prescribing guidance, a clear rationale and objectives should be articulated at the outset. The Medicines Management Commissioning Team reviews proposals and commissions the work to be undertaken.

2.6. Once initiated, the process for development/review of formulary chapters and/or prescribing guidance is set out in the remainder of this paper and is summarised in the following flow chart:

HSCB and PHA Process for the Development of a Formulary Chapter/Substantive Prescribing Guidance

Individual, group or organisation in HSC suggests the need for regional prescribing guidance on a particular issue, formulary chapter development, or a review of existing guidance

Proposer completes & submits a Proposal Template (Appendix A) to the MMCT

Approved
by MMCT?

No

Inform the proposer in writing.
Decisions can be reviewed if
necessary by Lead Directors together,
& at request of the proposer

Yes

- Medicines Management Office (MMO) seeks nominations for the Panel for Prescribing Advice (PPA) & arranges PPA meetings
- MMCT identify an HSCB and/or PHA lead officer for the document (and a Medicines Management lead pharmacist if they are not the lead officer)
- Lead pharmacist prepares a first draft of the document as outlined in 3.4.3

Panel for Prescribing Advice refines the document to produce a draft for consultation

MMO manages the process to send the document out for consultation to Trusts (via Chief Executives) for onward dissemination to Trust D&T Committees. MMO also emails the document to ABPI and EMIG requesting feedback on factual inaccuracies and scientific interpretation only. A final draft is then agreed by the PPA. MMO sends the final draft to the Prescribing Guidance Editorial Group (PGEG), with a summary of the process used to develop the document.

PGEG reviews the final draft and signs off:

- That the approved HSCB & PHA process to develop the document was followed
- That the clinical content is appropriate

Final version is sent to Trust D&T Committees seeking agreement to apply document (ideally all, but a majority of Trusts is acceptable)

Final version is copied to MMCT for noting

MMO prepares letter and the document is issued under HSCB name by the relevant Director(s) or published on NI Formulary website as appropriate

Notes:

Lead Directors – Medical Director, Director of Integrated Care, Director of Commissioning

D&Ts – Drug and Therapeutic Committees

MMO – Medicines Management Office

Document - Formulary Chapter/Regional Prescribing Guidance

Panel for Prescribing Advice (PPA) - for definition, refer to 3.4.1 of this document

Prescribing Guidance Editorial Group (PGEG) - for definition, refer to 3.6 of this document

NICE - National Institute for Health and Care Excellence

SMC -Scottish Medicines Consortium

3. Development

3.1. Individual, group or organisation in HSC suggests the need for regional prescribing guidance on a particular issue, formulary chapter development, or a review of existing guidance

In order for MMCT to consider whether or not to commission a formulary chapter or other prescribing guidance, the proposer must complete the proforma in **Appendix A**.

3.2. Proposer completes and submits a Proposal Template (Appendix A) to the MMCT

The proposer must provide details of the prescribing guidance topic or formulary chapter. The proposer is required to detail what guidance is currently available in the proposed area and why a regional piece of work is required. The proposal must also include what organisations and staff are needed on the Panel for Prescribing Advice which will develop the formulary chapter/prescribing guidance. If the formulary chapter/prescribing guidance is required within a specific time frame, this must also be specified.

3.3. Consideration of the proposal by MMCT

3.3.1. If the proposal is approved by MMCT, the process continues to the next stage

3.3.2. If the proposal is rejected by MMCT, the proposer is informed in writing of the decision. Decisions can be reviewed if necessary by Lead Directors (Director of Public Health, Director of Integrated Care) together, and at the request of the proposer

3.4. Membership and Formation of the Panel for Prescribing Advice and Development of Initial Draft

3.4.1. The Medicines Management Office (MMO) will set up the relevant Panel for Prescribing Advice .This will include the identification of a relevant chair; setting the terms of reference for the Panel for Prescribing

Advice; timescales for delivery; agreed output; identification of clinical leads and seeking nominations from Trusts and primary care. The MMO will ensure organisational, geographic and multidisciplinary spread as appropriate for the Panel for Prescribing Advice.

Panels for Prescribing Advice will typically consist of primary care and trust (e.g. medical and pharmacy) representatives with specialist clinical knowledge of the therapeutic area under discussion.

Panels for Prescribing Advice convened will have a 'task and finish' function, and their remit will be:

1. Systematically review the topic area to advise on rational product selection, prescribing guidance and use across primary and secondary care
2. Reach decisions using based upon clear and rational criteria applying the best evidence available.
3. Employ a collaborative multi-disciplinary approach to reach consensus.

Membership of Panels for Prescribing Advice involved in developing formulary chapters/prescribing guidance will be listed on the Medicines Management section of the HSC Board website. A declaration of interests must be submitted at the start of the process. At each subsequent meeting, the chair will ask members for any changes to the initial declaration(s) (**Appendix B**). A further declaration of interest must be made if a Panel for Prescribing Advice is reconvened to undertake further work/review.

3.4.2. At the outset, MMCT will identify an HSCB and/or PHA lead officer for the document (and a Medicines Management lead pharmacist if they are not the lead officer)

3.4.3. The lead pharmacist will prepare a first draft of the document.

The process for production of initial formulary chapter/prescribing guidance typically includes the following steps:

INFORMATION GATHERING

- Utilise NICE, BNF and other recognised regional formularies as the starting point to obtain the range of products within a therapeutic area
- Review the available evidence taking into account information such as NICE, and if NICE guidance is not available, then SMC guidance, or if not available, other credible guidance
- Review the other available information sources that may assist with the criteria detailed below including:
 - Information or results obtained from procurement processes for secondary care contracts where relevant. This information will only be considered in the context of the criteria outlined below, where it is of particular pertinence to patient care
 - Any feedback received from primary or secondary care
- Consideration of local prescribing patterns across primary and secondary care, aiming to improve quality by reducing inappropriate variation and to encourage consistency of care pathway arrangements across the patient population

CRITERIA TO BE CONSIDERED

When selecting products consider the following criteria as appropriate:

- Evidence of need
- Efficacy
- Safety
- Misuse impact potential
- Cost implications
- Patient acceptability
- Current prescribing patterns

3.5. Panel for Prescribing Advice refines the document to produce a final draft

The initial draft of the document is discussed by the Panel for Prescribing Advice; the meetings are minuted and changes are made by the Medicines Management lead pharmacist. Decision making will be informed by the checklist tool at **Appendix C** and the steps outlined in 3.4.3. Agreement is reached on a draft to be circulated for wider consultation.

3.6. Consultation

The draft formulary chapter/prescribing guidance will be emailed to Trust Chief Executives for onward dissemination to HSC Trust Drug and Therapeutic Committees requesting feedback on areas relevant to their expertise. A cover paper will be included with the draft document (**Appendix D**). This is a 6 week consultation period.

The draft formulary chapter/prescribing guidance will be also emailed to Association of British Pharmaceutical Industry NI (ABPI) and Ethical Medicines Industry Group (EMIG) for onward distribution to member pharmaceutical companies requesting feedback on factual inaccuracies and scientific interpretation only. This is a 6 week consultation period.

After the consultation process, a final draft is agreed by the Panel for Prescribing Advice. The Medicines Management office will then send the final draft to the Northern Ireland Prescribing Guidance Editorial Group, with a summary of the process used to develop the document (**Appendix E**).

The Prescribing Guidance Editorial group will be chaired by the HSCB Head of Pharmacy and Medicines Management in the first instance and will include

1. Trusts – 5 nominated representatives (via Chief Executives)
2. Primary Care - 5 GPs from HSCB and 1 appointed community pharmacist
3. Patient and Clients – 1 nominee from Patient and Client Council
4. A senior pharmacist from HSCB
5. A medical adviser (public health) from PHA
6. Regional Medicines Information Lead.

The group will be supported by the HSCB Medicines Management Team.

The roles and remit of the Prescribing Guidance Editorial Group are included in **Appendix G**.

3.7. Prescribing Guidance Editorial Group reviews final draft and signs off:

-that the approved process to develop the document was followed

-that the clinical content is appropriate.

The Prescribing Guidance Editorial Group will meet on a quarterly basis; meetings will be noted and the minutes, along with a table of decisions in relation to specific drugs, will be published on the Medicines Management website.

3.8. Final version emailed to the Trust D&T Committees seeking agreement to apply document

Trust D&T Committees should complete **Appendix F** to confirm agreement to apply document within their Trust (ideally all, but a majority of Trusts is acceptable).

3.9. Final version emailed to the Medicines Management Commissioning Team for noting

The final version of the document will be emailed to Medicines Management Commissioning Team for noting.

3.10. Medicines Management Office prepares letter and the document is issued under HSCB name by the relevant Director(s)

Once Medicines Management Commissioning Team has taken note of the document, it will be issued by the HSCB in paper and/or electronic formats with monitoring and audit as appropriate. New and updated formulary chapters will be uploaded to the NI formulary website.

Applications for Inclusion of a Drug in Formulary Chapter/Prescribing Guidance

3.10 Applications for new drug submissions will normally be considered at least six months after publication of a formulary chapter/prescribing guidance. Practitioners, HSC Trusts or the Pharmaceutical Industry can apply for consideration of any new medicine or indication to be included in the formulary chapter/prescribing guidance. Applications forms for this process can be found in **Appendix H (Pharmaceutical Industry) and I (clinicians)**. Decision making will be informed by the checklist tool **Appendix C**. Applications will be considered in line with the 'Prescribing Guidance Editorial Group Process for Dealing with New Drug Submissions' found in **Appendix J**

Regular updates on prescribing guidance/formulary chapters completed will be provided by the Medicines Management Team to key stakeholders

4. Implementation and Monitoring

4.1 MMCT will monitor the trends in prescribing of approved medicines. The HSC Board Medicines Management Team will develop a baseline position with respect to prescribing choices and will monitor uptake to determine impact of the formulary chapter/prescribing guidance. Reports on individual prescribing practice will continue to be made available to GPs and other prescribers, and to secondary care consultants when available.

4.2 MMCT will report progress and trends through the Commissioning Programme Board to the Senior Management Team of HSCB and, as required to the Governance Committee of the HSC Board.

5 Review

5.1 The formulary chapter/prescribing guidance will be reviewed and updated by the Medicines Management Team. A process of review is proposed which takes into account reactive review (where evidence has changed) and proactive review (where existing guidance is reviewed on an on-going basis).

Reactive Review

5.2 Minor amendments are those which do not require a change in drug choice. The outcome of the review may involve:

- Updated/amended prescribing note
- New prescribing note
- New caution
- Updated/amended dose

Minor amendments will be actioned by the Medicines Management Information Team. Changes are circulated electronically to the Prescribing Guidance Editorial Group for comments and approval where appropriate. Changes are made and uploaded to the NI Formulary website

5.3 Significant amendments include those which may be a result of the following:

- NICE CG or TA which significantly impacts on current prescribing practice
- Drug withdrawals or significant MHRA safety warning

The outcome requires a change in formulary drug – addition of new drugs or a deletion of existing drugs. A significant review of Prescribing Notes is also required.

These will be actioned by the Medicines Management Information Team who will propose changes and circulate electronically and/or table at the

Prescribing Guidance Editorial Group for discussion. If the Prescribing Guidance Editorial Group feel it is appropriate, advice is sought from a Panel for Prescribing Advice (which may need to be reconstituted/reformed). The Panel for Prescribing Advice may make minor changes or advise a redraft.

Following revisions and usual consultation, the Prescribing Guidance Editorial Group will provide the final approval of revised formulary chapter/prescribing guidance. Decisions will be noted and shared on the Medicines Management website.

Proactive Review

- 5.4 Each formulary chapter/prescribing guidance will be reviewed approximately every 2-3 years. The process for developing formulary chapters/prescribing guidance will be used in the proactive review process.
- 5.5 The revised formulary chapter/prescribing guidance will be updated, version control record updated and uploaded to the HSC Board and/or NI Formulary website.

6 Appeal

- 6.1 The decision of the Prescribing Guidance Editorial Group can be appealed if it is felt that the decision reached did not follow the published HSCB and PHA Process for Developing Prescribing Guidance.
- 6.2 An appeal must be lodged within 20 working days of publication of the formulary chapter/prescribing guidance or decision made and must detail the aspect of the process that was not followed and the grounds to support this contention.
- 6.3 The appeal will be assessed by a panel consisting of three members as follows:
 - Head of Corporate Services (chair)
 - Director of Integrated Care (where a GP has requested a decision be reviewed, the Director of Finance rather than the Director of Integrated Care will sit on the Panel)
 - Non-executive member of HSC Board or PHA Board
- 6.4 The Appeal Panel's role is to consider the process followed by NI Prescribing Guidance Editorial Group, not to hear new or different evidence.
- 6.5 The Appeals Panel will either:
 - 6.5.1 Uphold grounds for the appeal and ask MMCT to initiate a review; or
 - 6.5.2 Allow the determination of the Prescribing Guidance Editorial Group to stand.
- 6.6 The decision of the Appeal Panel will be communicated to the requestor of the appeal, the Panel for Prescribing Advice and the Prescribing Guidance Editorial Group and posted on the Medicines Management website within 5 working days.
- 6.7 Notwithstanding this process, requestors who are dissatisfied may make a complaint through the Board.

Appendix A

MMCT Proposal Template

Formulary Chapter/Prescribing Guidance Topic

What formulary chapter/prescribing guidance is already available?

Why is formulary chapter/prescribing guidance required?

What type of organisations, staff and other inputs are needed on the Panel for Prescribing Advice which will develop the formulary chapter/prescribing guidance ?

Is there a deadline by which the formulary chapter/prescribing guidance is required, and why?

Your name _____

Your title _____

Your email address _____

Your telephone number _____

Date _____

Appendix B

DECLARATION OF INTERESTS AND RECEIVED HOSPITALITY

Declared interest or received hospitality	Please state
Directorships, including non-executive Directorships held in private companies or PLCs (with the exception of those of dormant companies)	
Ownership, or part ownership, by self, spouse or partner, of private companies, businesses or consultancies held likely or possibly seeking to do business with the NHS	
Majority or controlling share holdings in organisations likely or possibly seeking to do business with the NHS	
A position of authority in a charity or voluntary body in the field of health and social care	
Any connection with a voluntary or other body contracting for NHS products or services including: <ul style="list-style-type: none">• share holdings or other interests in pharmaceutical companies• receipt of departmental, staffing or personal sponsorship from the pharmaceutical industry• engagement by the pharmaceutical industry to provide advice, undertake presentations, lectures or tours of instruction	
Any received hospitality exceeding £100 (this figure is for guidance purposes)	

Name:

Employing organisation:

Signed:

For the year to date:

Declaration of interests will be handled in line with the Board's Standing Orders (7.3.1)

<http://www.hscboard.hscni.net/board/HSCB%20Standing%20Orders%20-%20March%202013%20PDF%201-37MB.pdf>

Return to:

**Medicines Management Information Co-ordinator
HSCB Pharmacy and Medicines Management Team
2 Franklin Street
Belfast
BT2 8DQ**

Appendix C Checklist Tool for Prescribing Decision Making

Adapted from: A Prescription for Improving Drug Formulary Decision Making, Volume 9 Issue 5 May 2012, www.plosmedicine.org

A. Evidence of need

Is there a compelling need to add the drug to our formulary/prescribing guidance?

- What is the prevalence and importance of the condition the drug is intended to treat? What is the relevance of this drug to our population? Are there special subpopulations for which there may be a compelling need?
- What are the demonstrated shortcomings of existing therapy? Is there evidence that this drug overcomes problems in safety, efficacy, acceptability, or convenience that characterise existing therapy?
- What role does this drug play in addressing this need? What are the European Medicines Agency (EMA), or other international agencies' approved indications? What other claims for the drug are being made?
- What other therapeutic approaches (including non-drug alternatives) might reasonably be pursued instead?
- Is the drug needed for all the venues/settings for which it is being requested

B. Efficacy

What is the evidence to support the claims for this drug?

- What is the quality and strength of the evidence supporting the efficacy claims? How well designed are these studies?
- Are the claims (both on- and off-label) being made for this drug supported by the data presented?
- How relevant is the population in the published studies to our population and patients in whom it is likely to be used? Were patients like those we treat included in the clinical trials used to gain EMA, or other governmental regulatory approval, and will the drug's use likely be similar to patients where benefit is proven?
- To what extent are the benefits based on surrogate measures (i.e., haemoglobin A1c, low-density lipoprotein [LDL], serum sodium) rather than clinically relevant outcomes (e.g., mortality, quality of life, strokes)?
- Does the published (or unpublished) literature contain conflicting evidence about efficacy? Is there suggestion of selective publication, or selective sharing of only more favourable studies by those advocating formulary addition?
- What is the "marginal efficacy"—efficacy above and beyond other therapeutic alternatives?

- Do the efficacy studies use proprietary or manufacturer-developed scales that may bias the findings to give favourable results (e.g., specialised, manufacturer-developed quality of life instruments targeted to be responsive to the effects of a particular drug)?

C. Safety

What safety issues need to be considered?

- Is there a potential for look-alike, sound-alike name errors raised by or reported for this drug?
- Are there safety issues surrounding the administration or preparation requirements?
- What is the adequacy of the experience with the drug? What are the number and types of patients studied? How long has the drug been used to assure there is a demonstrated safety track record (since many adverse effects only appear after 5–10 years of use)?
- Are there suggestions of early warning signals (either in the literature, unpublished studies or reports, or theoretical concerns based on class effects) of potential safety concerns (e.g., reports of hepatotoxicity, nephrotoxicity, or drug–drug interactions, QT prolongation) that may be a red flag, cautioning against moving too quickly to approve the drug?
- What patient monitoring or other special precautions (e.g., pregnant women, renal insufficiency), are needed or required to use the drug safely? How difficult will it be for practitioners to comply with needed monitoring, and how likely are they to perform adequately?
- How strong is the evidence of this drug’s safety compared to other drugs in its class, or other drugs for the same indication currently on the market? What are the anticipated types of adverse events? How do the frequency, severity, preventability, and ameliorability of these adverse events compare across alternative drugs for this indication?

D. Misuse impact potential

If placed on the formulary/prescribing guidance, what is the potential for misuse or overuse?

- Is the drug subject to intensive marketing to either consumers or prescribers for questionable and/or off-label indications that may lead to excessive or inappropriate use?
- Is there evidence or worry that the drug will be subject to excessive or unrealistic patient demand and expectation? Are there concerns that advertising will play a role in patient demand? Are industry-funded patient

advocacy groups aggressively lobbying for the drug, possibly creating pressures for premature or overuse?

- Is there uncertainty or difficulty in accurately diagnosing the condition that is the indication for this drug, leading to potential overuse or inappropriate use of the drug?
- Are there concerns for widespread “off-label” usage?
- Might the expansion of indications to new manufacturer-promoted syndromes play a role in this drug’s usage and potential for overuse?
- Is there experience (in HSC or published literature) with similar drugs and situations suggesting there may be overuse of this agent?
- Is there evidence that any of the active ingredients in the drug is addictive or habit forming?

E. Cost Implications

Can we justify the cost of this drug?

- How much will it cost? Are there other relevant costs such as additional preparation, storage, administration, monitoring, or other downstream costs beyond simple acquisition costs?
- What is the cost and burden of additional monitoring requirements in safely using this drug?
- What are the comparative costs of other alternatives (e.g., are generics available)?
- Will a competitor/comparable drug soon become available generically?
- If there is an added cost associated with using this drug, is there a significant clinical benefit that justifies the added expense?
- What other pricing issues (rebate deals, market share or exclusivity requirements, some of which may not be transparent) may impact purchasing this drug for patients in NI? Will the price be raised later once we switch over to this drug (“bait and switch” pricing tactics)?
- What costs are involved in switching patients currently on another drug that we may be substituting this medication for (additional visits, monitoring)?
- How do the acquisition and above additional costs compare to evidence of cost savings (reduction in admissions, other expenditures)?

F. Decision-making information, calculations, timing, and process

What is the strength and quality of evidence and information available to the Group?

- What is the source (i.e., from pharmaceutical sales representative versus independent review), completeness, timeliness, and quality of the information the Group has available to make a decision at this time?
- Has an independent drug monograph review been prepared for the Group (e.g., by a pharmacist or drug information service)? If yes: Are the monograph and other information upon which decisions are being made adequate, or are there unanswered questions (such as those raised in this document) that require additional information?
- Are there reviews by other formulary or guideline committees or international drug bulletins whose judgments and decisions can also help inform our discussion and decision?
- Are there outstanding questions that may be answered by additional information (e.g., pending research trials) that may warrant deferring a decision?

What is the status and quality of the review process and use in NI?

- Has the drug previously been reviewed by the Group? If yes what were the issues raised in prior review, discussion, and decision? Was the process a fair and high quality group decision?
- What does the primary care prescribing data indicate re use in Northern Ireland?
- Have the requisite subcommittees and key and knowledgeable specialists been consulted, how have they weighed in on the decision?
- Has there been undue influence or bias impacting the decision-making process? Have all conflicts of interest (financial, research funding) been disclosed related to the requester, committee members, or those involved with evaluating this drug's formulary status (e.g., desire to please a high income-generating clinician)?
- What is desirability of approval now versus delaying approval pending additional information?
- Which clinicians should be permitted to use this drug and in what clinical venue?
- Should there be restrictions (e.g., clinical prior approval or other mechanisms) placed on this medication (based on indication, safety, clinical, or cost outcomes)? If so, what should they be and how easily can they be operationalised and made to work effectively minimising administrative burdens?

- Are there guidelines and/or electronic clinical decision support alerts that could help ensure safe and appropriate use of this medication; how can they best be operationalised?

G. Patient acceptability

- Are there any clinically important drug interactions?
- Are there any particular groups of patients for whom the drug is contraindicated or where it should be used with caution?
- Are there some patients who may particularly benefit?
- What are the considerations from the patient's perspective?

Appendix D Template for Formulary Chapter/Prescribing Guidance Cover Paper

1. Title of Formulary Chapter/Prescribing Guidance

2. Version record control

3. Expected action by Trust Drug & Therapeutics Committees

4. Context/Introduction

5. Panel for Prescribing Advice who developed and signed off Formulary Chapter/Prescribing Guidance including name of Chair

6. Indicate concordance with NICE and specify where document differs from NICE

7. Executive Summary of Formulary Chapter/Prescribing Guidance

8. Equality Implications

9. Financial Implications

10. Recommendation

11. Submitted by/Job Title

Appendix E Formulary Chapter/ Prescribing Guidance Process Summary

Step	Process	Date completed
Convene or re-convene Panel for Prescribing Advice clinical expertise in the therapeutic area	<p>A letter to each of the 5 HSC Trusts sent seeking nominations for the group</p> <p>GP representation sought from those with a specialist interest in the particular clinical area</p>	
Date arranged for first meeting of Panel for Prescribing Advice	Medicines Management support staff circulate a number of potential dates and meeting booked	
Initial drafting	Initial draft of document produced by Medicines Management Information Team taking into account NICE, other national guidance and other HSC Board guidance where appropriate. Initial draft is shared with the Panel for Prescribing Advice for comments	
First meeting of Panel for Prescribing Advice	<p>Declaration of interest forms completed and stored for future reference</p> <p>Each section of the document is discussed and relevant changes made</p>	
Consulting	<p>Draft document to be shared with Trusts (via Chief Executives) for onward dissemination to Drug & Therapeutic Committees requesting feedback and to the pharmaceutical industry representatives requesting feedback on factual inaccuracies and scientific interpretation only</p> <p>This is a 6 week consultation period</p>	

Collation of responses	A table is drafted with all responses to the consultation...this is circulated to the Panel for Prescribing Advice for discussion at the next meeting	
Final drafting	The Panel for Prescribing Advice meets again, discusses each of the comments and makes decision about these comments; final draft agreed. This final draft is e-mailed to the Northern Ireland Prescribing Guidance Editorial Group	
Agreeing content	<p>NI Prescribing Guidance Editorial Group agrees and finalises the content of the document</p> <p>Minutes of this meeting are recorded and published on the Medicines Management website. The decisions made by the Panel for Prescribing Advice to be circulated prior to the meeting and any conflicting opinions can be discussed and clarified</p> <p>Final version is emailed to Trust D&T Committees seeking agreement to apply document</p>	
Approval of process	Final version of document agreed and finalised. Copied to MMCT for noting	
Dissemination	Letter issued to Health and Social Care from Health and Social Care Board.	

Appendix F

HSC Trust Drug and Therapeutics Committees' Agreement to Apply Formulary Chapter/Prescribing Guidance Documents

Title of Formulary Chapter/Prescribing Guidance

Version Reference:

Date received by HSC Trust:

Trust: BHSCT NHSCT SEHSCT SHSCT WHSCT
(Please Circle)

Signature:

Date:

Agree to Apply/ Do not agree to apply (please provide details below)
(Please Circle)

Comments:

Appendix G

Roles/Remit of the Prescribing Guidance Editorial Group

The title of the group will be the Prescribing Guidance Editorial Group

The aim of the group will be:

1. Consider and review the process for developing formulary chapters/regional prescribing guidance
2. Provide an assurance that the process has been undertaken robustly and that due process has been followed
3. Make decisions on the final content paying full consideration to the consultation responses and the criteria for decision making

The membership of the group will be:

- Chair – Head of Pharmacy and Medicines Management, HSCB
- Trusts – 5 nominated representatives (via Chief Executives)
- Primary Care - 5 appointed GPs and 1 appointed community pharmacist
- Patient and Clients – 1 nominee from Patient and Client Council
- A senior pharmacist from HSCB
- A medical adviser (public health) from PHA
- Regional Medicines Information Lead

Quorum will be 9 members

The group will be supported by the HSCB Medicines Management Team

The Group will meet quarterly and meetings will be noted with approved minutes being made publicly available

The Group will be accountable to the HSC Board, via MMCT to the Commissioning Programme Board. A regular report of its activity will be provided to the Commissioning Programme Board.

Appendix H

Request for a Medicine to be Added to the Northern Ireland Formulary Chapter/ Prescribing Guidance



Pharmaceutical Industry Form

INTRODUCTION

The Northern Ireland HSCB & PHA Process for Developing Prescribing Guidance states that practitioners, HSC Trusts or the Pharmaceutical Industry can ask for consideration of any new medicines for inclusion in the Northern Ireland Formulary/ Prescribing Guidance or the addition of a new indication for an existing medicine.

The following documentation should be completed in **full** and submitted with the relevant clinical evidence.

SECTION 1: MEDICINE DETAILS

Generic / Approved name:

Brand name:

Strength/Formulation/Route of Administration:

Manufacturer:

SECTION 2: PLACE IN THERAPY

Licensed Indication(s) [included in the Summary of Products Characteristics (SPC)]:

Indication(s) for proposed use:

Current formulary choices for proposed indication:

Perceived advantages over current therapy:

Are there any perceived disadvantages over current therapy:

Place in therapy (tick all boxes which apply):

First line choice

Second line choice

Replace a current formulary choice (state which medicine is to be replaced)

.....

For restricted use in specific patient groups (provide details)

Tick one box which applies:

Suitable for prescribing / initiation in primary care

Initiation restricted to or on the advice of a specialist

To be used in accordance with protocol (attach a copy of the protocol with the submission)

SECTION 3: NATIONAL GUIDANCE

Has the medicine / formulation / indication been evaluated by the following bodies:

National Institute of Health and Care Excellence (NICE)

Scottish Medicines Consortium (SMC)

Scottish Intercollegiate Guidelines Network (SIGN)

All Wales Medicines Strategy Group

Give details of place in therapy recommended by the bodies above:

SECTION 4: CLINICAL EVIDENCE

Provide details below of key trials that support the submission (attach copies of up to 3 (maximum) relevant references or information in support of the submission)

SECTION 5: COMPARATIVE SAFETY

Provide details of any safety issues regarding this medicine compared to current formulary choices

SECTION 6: TOLERABILITY & ACCEPTABILITY

Provide details below of key information on patient experience regarding this medicine compared to current formulary choices

SECTION 7: SERVICE IMPLICATIONS

Cost of treatment (annual cost or cost of course of treatment if less than 1 year) (state both hospital and primary care costs if the costs are different in the two settings)

Likely duration of treatment

Overall annual /course costs in one year

Additional service implications e.g. specialist assessment, monitoring requirements (state if to be undertaken in secondary care or primary care), aseptic unit preparation, nursing time

SECTION 8: ADDITIONAL INFORMATION

Provide any additional information which may assist in the decision making process

SECTION 9: DETAILS OF SUBMITTING PHARMACEUTICAL COMPANY

Name:

Position within Company:

Pharmaceutical Company:

Member of ABPI:

Send the completed form and any supporting evidence to:
Medicines Management Information Team
2 Franklin Street, Belfast
BT2 8DQ

Or send via e-mail to medicines.management@hscni.net

FOR USE OF HSCB ONLY

Final decision	Date	Rationale behind decision

NAME AND SIGNATURE OF CHAIR OF PRESCRIBING GUIDANCE EDITORIAL GROUP

	Date
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Appendix I

Request for a Medicine to be Added to the Northern Ireland Formulary Chapter/Prescribing Guidance

Practitioner/ HSC Trusts Form



INTRODUCTION

The Northern Ireland HSCB & PHA Process for Developing Prescribing Guidance states that practitioners, HSC Trusts or the Pharmaceutical Industry can ask for consideration of any new medicines for inclusion in the Northern Ireland Formulary/ Prescribing Guidance or the addition of a new indication for an existing medicine.

The following documentation should be completed in **full** and submitted with the relevant clinical evidence.

SECTION 1: MEDICINE DETAILS

Generic / Approved name:

Brand name:

Strength/Formulation/Route of Administration:

Manufacturer:

SECTION 2: PLACE IN THERAPY

Licensed Indication(s) [included in the Summary of Products Characteristics (SPC)]:

Indication(s) for proposed use:

Current formulary choices for proposed indication:

Perceived advantages over current therapy:

Are there any perceived disadvantages over current therapy:

Place in therapy (tick all boxes which apply):

First line choice

Second line choice

Replace a current formulary choice (state which medicine is to be replaced)

.....

For restricted use in specific patient groups (provide details)

Tick one box which applies:

Suitable for prescribing / initiation in primary care

Initiation restricted to or on the advice of a specialist

To be used in accordance with protocol (attach a copy of the protocol with the submission)

SECTION 3: NATIONAL GUIDANCE

Has the medicine / formulation / indication been evaluated by the following bodies:

National Institute of Health and Care Excellence (NICE)

Scottish Medicines Consortium (SMC)

Scottish Intercollegiate Guidelines Network (SIGN)

All Wales Medicines Strategy Group

Give details of place in therapy recommended by the bodies above:

SECTION 4: CLINICAL EVIDENCE

Provide details below of key trials that support the submission (attach copies of up to 3 (maximum) relevant references or information in support of the submission)

SECTION 5: COMPARATIVE SAFETY

Provide details of any safety issues regarding this medicine compared to current formulary choices

SECTION 6: TOLERABILITY & ACCEPTABILITY

Provide details below of key information on patient experience regarding this medicine compared to current formulary choices

SECTION 7: SERVICE IMPLICATIONS

Cost of treatment (annual cost or cost of course of treatment if less than 1 year) (state both hospital and primary care costs if the costs are different in the two settings)

Likely duration of treatment

Overall annual /course costs in one year

Additional service implications e.g. specialist assessment, monitoring requirements (state if to be undertaken in secondary care or primary care), aseptic unit preparation, nursing time

SECTION 8: ADDITIONAL INFORMATION

Provide any additional information which may assist in the decision making process

SECTION 9: DETAILS OF SUBMITTING CLINICIAN / SUPPORTING PHARMACIST

Name:

Designation:

Hospital Department, LCG or GP Practice Details:

Supporting Pharmacist Name (if appropriate):

Designation:

SECTION 10: DECLARATION OF INTERESTS (IN THE LAST 12 MONTHS ONLY)

It is important that any interests in pharmaceutical companies that may be relevant to this submission are declared.

Declared interest or received hospitality	Please state
Directorships, including non-executive Directorships held in private companies or PLCs (with the exception of those of dormant companies)	
Ownership, or part ownership, by self, spouse, or partner, of private companies, businesses or consultancies held likely or possibly seeking to do business with the NHS	
Majority or controlling share holdings in organisations likely or possibly seeking to do business with the NHS	
A position of authority in a charity or voluntary body in the field of health and social care	
Any connection with a voluntary or other body contracting for NHS products or services including: <ul style="list-style-type: none"> • share holdings or other interests in pharmaceutical companies • receipt of departmental, staffing or personal sponsorship from the pharmaceutical industry • engagement by the pharmaceutical industry to provide advice, undertake presentations, lectures or tours of instruction 	
Any received hospitality exceeding £100 (this figure is for guidance purposes)	

Clinician's Signature	
Date	
Pharmacist's Signature	
Date	

Send the completed form and any supporting evidence to:
 Medicines Management Information Team
 2 Franklin Street, Belfast, BT2 8DQ
 Or send via e-mail to medicines.management@hscni.net

FOR USE BY THE HSCB ONLY

Final decision	Date	Rationale behind decision

NAME AND SIGNATURE OF CHAIR OF PRESCRIBING GUIDANCE EDITORIAL GROUP

	Date
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Appendix J

Prescribing Guidance Editorial Group Process for Dealing with New Drug Submissions

The HSCB and PHA Process for Developing Prescribing Guidance and Formulary Chapters allows for the application of new drugs to be included in the NI Formulary in a number of circumstances:

*“Applications for new drug submissions will normally be considered at least six months after publication of a formulary chapter/prescribing guidance. Practitioners, HSC Trusts or the Pharmaceutical Industry can apply for consideration of any new medicine or indication to be included in the formulary chapter/prescribing guidance. Applications forms for this process can be found in **Appendix H (Pharmaceutical Industry) and I (clinicians)**. Decision making will be informed by the checklist tool **Appendix C**.*

New drug submission will be a standing agenda item for the quarterly Prescribing Guidance Editorial Group (PGEG) meetings.

New drugs submissions will only be tabled at PGEG if they are received 4 weeks prior to the meetings (dates of PGEG will be published on the Medicines Management section of the HSCB website). New drug submissions must be typed and submitted in an electronic format.

The Medicines Management Team will review the new drug submissions and consider appropriateness of the application. New drug submissions may be rejected at this point in the process if:

- The new drug submission is for a therapeutic area that is not covered by the NI Formulary at the current time
- The new drug submission is for a therapeutic area that is currently undergoing proactive review (every 2 years). Applications will be considered at least 6 months after publication of the updated chapter

- The new drug submission is for a specialist medication which is outside the remit of the NI Formulary which aims to cover 70% of all prescribing choices in primary/secondary care
- The new drug submission is for a drug which has been discussed by the Prescribing Guidance Editorial Group within the previous 6 months and a negative decision reached.
- The new drug submission is for a drug which is not currently accepted for prescribing under the NI Managed Entry arrangements

In each of the above situations, the chair of the Prescribing Guidance Editorial Group will respond to the submitter of the new drug requests explaining why the new drug submission is not being brought forward to PGEG for consideration.

If the new drug submission is to be tabled at PGEG, it will be included under the standing item “New Drug Submissions” and relevant papers will be circulated to the members 2 weeks prior to the meeting.

Following discussion of the new drug application at PGEG, the chair of the group will inform with submitter within 2 weeks of the decision of the PGEG.

If the decision has been successful, the new drug will be added to the relevant NI Formulary chapter within 4 weeks.