## Northern Ireland Formulary Public Consultation

The Health and Social Care Board has been set a ‘Priorities for Action’ target to establish a Formulary for Northern Ireland.

### What is a Formulary?

A Formulary is fundamentally a preferred list of medicines which your doctor would choose to prescribe for you if appropriate. The medicines are chosen on the basis of the available evidence for their effectiveness (ability to treat the condition), their safety (reduced likelihood of causing harmful side-effects) and cost.

Cost is included as a factor when two medicines treat the condition and are equal in effectiveness and safety.

### What does a Formulary mean to me?

If you are currently taking a medicine that is not on the Formulary your medicine will still be available to you on prescription.

You may be asked to change over to the Formulary medicine choice if your doctor feels that it is appropriate for you to do so.

If you go to see your doctor with a condition that is covered by one of the Formulary chapters, it is likely that you will be prescribed one of these medicines – normally the first line choice, unless there is a reason why the preferred medicine would not be suitable for you.

**Northern Ireland Formulary Public Consultation**

The Health and Social Care Board is putting in place arrangements to manage the introduction of the Formulary and the purpose of this consultation is to seek your views on the following:

- The remit of the Northern Ireland Formulary
- The process that the Health and Social Care Board will use to develop the Formulary
- Implementation and review of the Formulary
- Equality implications (Section 75)

Whilst this consultation is mainly targeted at healthcare professionals within Health and Social Care in Northern Ireland, the Health and Social Care Board welcomes written responses on the above arrangements from anyone else who may be interested.

Responses will help shape how the Health and Social Care Board develop, implement and review the Formulary in Northern Ireland.

Responses should be returned to:

Medicines Management Information Team
2nd Floor, Business Services Organisation
2 Franklin Street
Belfast
BT2 8DQ

Or via email to medicines.management@hscni.net by Friday 2 September 2011

This document can be made available on request in an alternative format, for example, large print, Braille, disk, audio cassette, easy read or in other languages to meet the needs of those whose first language is not English.

In accordance with Freedom of Information Act 2000, the Health and Social Care Board will publish a summary of responses which may be disclosed on request.

Information provided from consultees is unlikely to be treated as confidential except in very particular circumstances.

## Northern Ireland Formulary Consultation on Remit, Process and Review

The Health and Social Care Board is seeking views on the process used to establish the Northern Ireland Formulary.

Specifically, views are sought on the following key areas:

1. Remit (Appendix A)
2. Process for Northern Ireland Formulary Development (Appendix B)
3. Implementation and Review (Appendix C)

Please add your comments after each question as set out in each section.

1. Remit

- Do you agree with the remit of the Northern Ireland Formulary as detailed in Appendix A of this consultation?

- Do you agree that the Formulary should be expected to cover 70% of prescribing choices?

- Do you agree that the Northern Ireland Formulary should apply equally to both primary (General Practitioners) and secondary care (hospitals)?

- Do you agree with the principle that the Northern Ireland Formulary medicines should be the first line recommendations for indications as they are described in both primary and secondary care?

- Should anything be added, amended or deleted from the remit of the Northern Ireland Formulary?

- Do you have any additional comments on the remit of the Northern Ireland Formulary?

2. Process

- Do you agree with the process that the Health and Social Care Board has used to develop the Northern Ireland Formulary (as detailed in Appendix B)?

- Is there anything that you suggest should be added, amended or deleted from the process?

- Do you have any additional comments on the Northern Ireland Formulary process?

3. Implementation and Review

- Do you agree with the implementation process as described by the Health and Social Care Board (as detailed in Appendix C)?

- Do you agree with the review process as described by the Health and Social Care Board?

- Is there anything that you suggest should be added, amended or deleted from the implementation and review process?

- Do you have any additional comments on the implementation and review of the Northern Ireland Formulary?

## Equality Implications

The Health and Social Care Board has screened a draft therapeutic chapter of the Northern Ireland Formulary and did not find any aspect of the policy to adversely impact on any equality group within the population of Northern Ireland. The policy intention is to improve the use of medicines. Medicines are used by older people and those with long term conditions. Better use of medicines will improve the care of these client groups and other related groups e.g. those with caring responsibilities.

The Health and Social Care Board seeks the views of the public and employees within Health and Social Care as to whether the implementation of the Northern Ireland Formulary impacts on any equality group.

Are the policy proposals for the Northern Ireland Formulary likely to have an adverse impact on equality of opportunity on any of the nine equality groups identified under Section 75 of the Northern Ireland Act 1998?

Yes No (please highlight)

If you answered “yes” to this question please state the group or groups and provide details of any supporting qualitative or quantitative evidence.

Have the needs of the Section 75 categories been fully addressed in the proposals?

Yes No (please highlight)

If you answered “no” to this question please outline the reasons for your answer.

Is there an opportunity for the policy to better promote equality of opportunity or good relations?

Yes No (please highlight)

If you answered “yes” to this question please give details as to how.

Please use the space below to insert any further comments, recommendations or suggestions you would like to make in relation to the Northern Ireland Formulary.

## Appendix A

## Northern Ireland Formulary – Background and Remit

### Background

In the 2001 Medicines Management Report, “A Spoonful of Sugar”, the Audit Commission recommended that joint primary and secondary care formularies should be developed. Such formularies when properly designed and implemented provide rational, clinically appropriate, safe and cost effective medicine prescribing. They can also provide opportunities for health professionals to identify the factors which influence medicine selection and act as drivers for the implementation of evidence-based practice. Although the overall effect of formularies should be to reduce medicine costs, some appropriate prescribing can lead to increased medicine expenditure in certain therapeutic areas, for example, cardiovascular disease prevention and sometimes the medicines of first choice in a class are not the least expensive.

Joint formularies will also act as mechanisms to increase generic dispensing rates. The Appleby Report (2004) criticised the low level of generic dispensing in Northern Ireland as being nearly 30% lower than the average in England. This has improved over the last five years and by November 2010 it was 61%, much closer to the United Kingdom average of 66% (2009). However, generic dispensing by general practitioners in Northern Ireland varies between 46% and 70% so there is room for improvement in a number of GP practices.

A Northern Ireland Regional Formulary would bring together the various national sources of information – National Institute for Health and Clinical Excellence, Scottish Medicines Consortium, National Prescribing Centre and the Cochrane Collaboration, together with formularies from other regions and local prescribing initiatives to produce a list of medicines and therapeutic options which would attempt to set standards for best clinical practice. For the first time in Northern Ireland we would be able to provide a regional mechanism for a prescribing interface between primary and secondary care which would result in fewer alterations in medicine therapy and reduce the risk of prescribing errors and adverse effects.

Three important factors will influence the nature of a Joint Formulary:

1. 80% of prescribing takes place in primary care.

2. The nature and extent of primary care is strongly influenced by clinicians in secondary care.

3. Prescribing errors are most common at the primary care and secondary care interface.

The Formulary, as commissioned, is designed to provide evaluated advice drawn from the available evidence on the most appropriate medicines to be prescribed across the therapeutic spectrum. In this context, it embraces the need to ensure consistency and continuity of prescribing across primary and secondary care and the consideration of medicines to be 'appropriate' from both clinical and cost-effectiveness perspectives. It clearly stands therefore as a significant corporate body of guidelines to support therapeutic practice and indeed wider prescribing governance.

Emanating from the Formulary, the Heath and Social Care Board may include Formulary monitoring as a quality indicator of medicines management within the Health and Social Care sectors. That said, there is clear recognition that individual patients may require medicines which lie outside recommended first line treatments and that concept is already encapsulated within the current therapeutic guideline publications. The Health and Social Care Board would, however, expect the majority of patients to be treated with the recommended first line choices while maintaining the ability to prescribe alternative treatments where individual cases warrant their use.

**Remit**

The Formulary is intended to be used across both primary and secondary care sectors in Northern Ireland to ensure consistency and continuity of supply.

The Formulary will provide all prescribers with guidance on first and second choice medicines (where appropriate). The selection will be based on clinical effectiveness, safety, cost effectiveness and patient acceptability, taking into account National guidance where appropriate.

The Formulary would bring together the various national sources of information, for example, National Institute for Health and Clinical Excellence, Scottish Medicines Consortium, National Prescribing Centre and the Cochrane Collaboration, to produce a list of medicines and therapeutic options which would attempt to set standards for best clinical practice. Where National guidance is not available, advice will be sought from the relevant clinical expert groups and/or clinicians with expertise in the therapeutic area to be reviewed.

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. The Formulary 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.

Adherence to the Formulary is strongly recommended in both primary and secondary care but it is recognised that there will be patients for whom a more extensive and complex medicine regimen is more appropriate, most notably in specialist care settings.

Non-formulary medicines are both appropriate and justifiable when there are contraindications to Formulary medicines or when patients require further medicines in addition to recommended first and second choice medicines. These clinical examples require clear communication between primary and secondary care.

The Formulary will be developed in stages equating to therapeutic British National Formulary chapters and these therapeutic areas will be prioritised based on frequency of use, impact on the prescribing budget, prescribing risk and overall therapeutic importance. The Formulary is not designed to replace the British National Formulary and all prescribers should continue to refer to it as the main source of medicine information.

The Formulary will also contain prescribing notes that highlight key messages about the medicines and/or the conditions being treated. Algorithms and more complex therapeutic topics will be referenced but not necessarily included in the Formulary except where appropriate.

Only new medicines which have Scottish Medicines Consortium and/or National Institute for Health and Clinical Excellence approval (with subsequent endorsement in Northern Ireland by the Department of Health, Social Services and Public Safety) can be added to the Formulary. Medicines with Scottish Medicines Consortium and/or National Institute for Health and Clinical Excellence approval will not be automatically included within the Formulary – consideration will be given to see if the medicine should be included as a first or second choice medicine within the therapeutic area reviewed. Medicines which may be considered as specialist may be considered as non-formulary medicines. Medicines awaiting Scottish Medicines Consortium or National Institute for Health and Clinical Excellence review will be considered as non-formulary items and those not accepted will remain excluded.

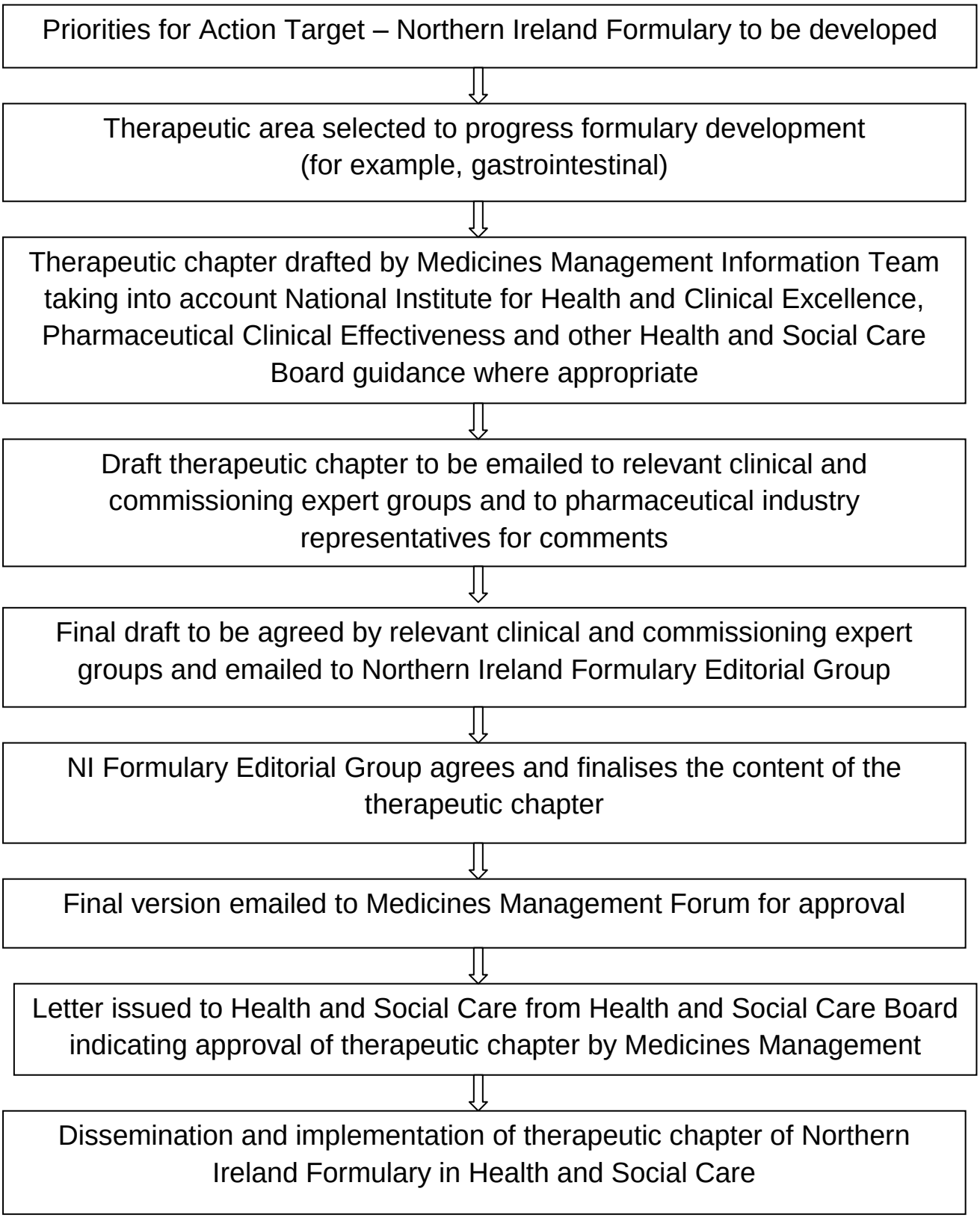
Generic names will be used except when proprietary names are more appropriate.

In some therapeutic areas, regional specialist groups are already developing and implementing prescribing guidance, for example, antimicrobial prescribing guidelines for primary and secondary care. In these cases these guidelines will be referenced and linked to from the Formulary.

The Formulary will be regularly updated and reviewed by the Formulary Editorial Subgroup with input from relevant clinical experts (see Implementation and Review section) and will be endorsed by the Medicines Management Forum.

## Appendix B

## Flowchart Capturing Process for Northern Ireland Formulary Development



1. *Priorities for Action Target – Northern Ireland Formulary to be developed for prioritised therapeutic areas*

2. *Therapeutic area selected to progress formulary development (for example, gastrointestinal)*

The Formulary will be developed in stages equating to therapeutic British National Formulary chapters and these therapeutic areas will be prioritised based on frequency of use, impact on the prescribing budget, prescribing risk and overall therapeutic importance.

3. *Therapeutic chapter drafted by Medicines Management Information Team taking into account National Institute for Health and Clinical Excellence, Pharmaceutical Clinical Effectiveness and other Health and Social Care Board guidance where appropriate*

The next stage would be to examine the prioritised sections of the various United Kingdom formularies to identify areas where there is strong agreement on the choice of medicines. For example, most formularies reviewed recommend omeprazole as first choice and lansoprazole as second choice proton pump inhibitor in the gastrointestinal section. Some areas have less agreement but in general there is at least a 95% concordance with the choice of medicines in the various formularies. Any other information should be taken into consideration, such as, National Institute for Health and Clinical Excellence, Pharmaceutical Clinical Effectiveness and other Health and Social Care Board guidance, where appropriate. Links to these sources should be able to be accessed from the Formulary section on the Health and Social Care Board website.

An initial draft will then be produced taking account of efficacy, patient acceptability, safety, cost effectiveness and clinical evidence.

4. *Draft therapeutic chapter to be e-mailed to relevant clinical and commissioning expert groups and to pharmaceutical industry representatives for comments*

The draft chapter should be emailed to the relevant clinical and commissioning expert groups requesting feedback on areas relevant to their expertise. Some therapeutic chapter reviews may require being emailed to more than one expert group or to more than one group of health care professionals with expertise in the therapeutic area concerned, for example, Central Nervous System which would require mental health specialists, pain specialists, Care of the Elderly and addiction services to be involved.

Membership of the clinical and commissioning expert groups includes hospital specialists, general practitioners, clinical pharmacologists and pharmacists and their names will be listed on the Formulary section of the Health and Social Care Board website. Any conflicting commercial interests must be declared before becoming involved.

The initial lists of well-established medicines will be largely based on the choices of formularies agreed elsewhere in the United Kingdom and on the choices endorsed by specialists in the clinical and commissioning expert groups.

It is not envisaged that any medicines will be included unless they have the support from recognised local, national or international bodies involved with cost effective medicine prescribing. All newly licensed medicines will require Scottish Medicines Consortium and/or National Institute for Health and Clinical Excellence approval before they are considered suitable for inclusion. Medicines with Scottish Medicines Consortium and/or National Institute for Health and Clinical Excellence approval will not be automatically included within the Formulary; consideration will be given to see if the medicine should be included as a first or second choice medicine within the therapeutic area reviewed. Medicines which may be considered as specialist may be considered as non-formulary medicines. Medicines awaiting Scottish Medicines Consortium or National Institute for Health and Clinical Excellence review will be considered as non-formulary items and those not accepted will remain excluded.

5. *Final draft to be agreed by relevant clinical and commissioning expert groups and emailed to Northern Ireland Formulary Editorial Group*

The Medicines Management Information Team will collate the comments received from the clinical and commissioning expert groups and seek approval on the suggested amendments as appropriate.

The final draft will then be emailed to the Northern Ireland Formulary Editorial Group for review.

6. *Northern Ireland Formulary Editorial Group agree and finalise the content of the therapeutic chapter*

The role of the Northern Ireland Formulary Editorial Group is as a reference group and its main role will be to decide on the structure and format of the Formulary, the criteria for inclusion and the adjudication and quality assurance issues to ensure the final version of the chapter meets the agreed criteria.

Membership of the Formulary Editorial Group will encompass Medicines Management Information Team, COMPASS Editorial Group, Regional Medicines Information and nominees from Health and Social Care Trusts, for example, Health and Social Care Trust Medicine and Therapeutics Committee nominees. Members from the clinical and commissioning expert groups may be invited to attend to present the final draft of the therapeutic area to the Editorial Group and to answer queries and address concerns, as appropriate.

The Northern Ireland Formulary Editorial Group will review the final draft agreed by the clinical and commissioning expert groups. Any controversial issues will be addressed and a final decision made by the Northern Ireland Formulary Editorial Group.

7. *Final version emailed to the Medicines Management Forum for approval*

The final version of the therapeutic chapter will be emailed to Medicines Management Forum members for their consideration and approval.

8. *Letter issued to Health and Social Care from the Health and Social Care Board indicating approval of therapeutic chapter by Medicines Management Forum*

Once Medicines Management Forum approval is made, the Health and Social Care Board will issue a letter to Health and Social Care advising of the details of the approved therapeutic chapter. The chapter will also be uploaded to the Medicines Management section of the Health and Social Care Board website.

9. *Dissemination and implementation of therapeutic chapter of Northern Ireland Formulary in Health and Social Care*

The members of the clinical and commissioning expert groups will have responsibility for ensuring that the information detailed in the letter from the Health and Social Care Board and the corresponding therapeutic chapter is implemented in their respective organisation.

The Health and Social Care Board's Pharmacy and Medicines Management Team will facilitate this process where appropriate, most notably in primary care.

## Appendix C

## Implementation and Review

### Implementation

Post Medicines Management Forum approval the Health and Social Care Board will issue a letter to Health and Social Care detailing the implementation requirements for the approved therapeutic chapter.

The Health and Social Care Board will monitor the trends in prescribing of approved formulary medicines.

### Regular Review

A robust process of revision and updating is essential since a Formulary tends to lose impact if a regular review of contents is not undertaken.

The Formulary will be reviewed and updated by the Medicines Management Information Team, where appropriate, in line with new national or regional guidance or secondary care procurement practices. The proposed amendments will be considered for approval by the relevant clinical and commissioning expert groups. The Northern Ireland Formulary Editorial Group will review any revised drafts agreed by the expert groups.

Minor changes to a therapeutic chapter, for example, dosage change, proprietary name change, may not require input from the relevant clinical and commissioning expert groups. In these situations, the Formulary Editorial Group will review and approve the changes.

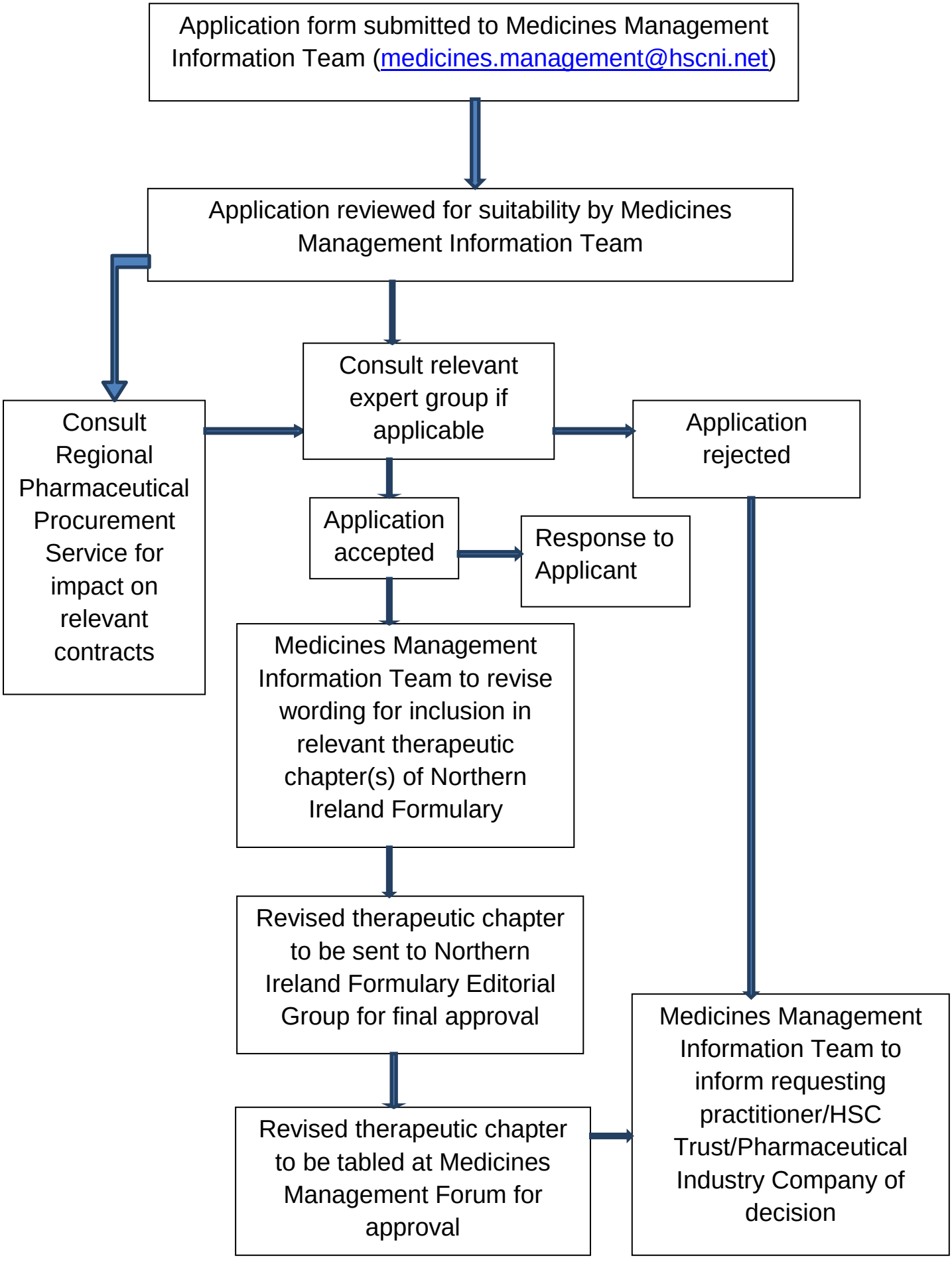
A more comprehensive review of the Formulary should be carried out every five years.

Routine horizon scanning will be carried out and the implications for the Formulary will be considered where appropriate.

## Ad Hoc Review – Applications for Inclusion in the Northern Ireland Formulary

The following flowchart details the process for applications from practitioners, Health and Social Care Trusts or the Pharmaceutical Industry to follow for consideration of any new medicine or indication. This process should also be followed for any medicines to be removed or amended in light of safety alerts or medicine product license withdrawals.

All evidence referred to in the application must be provided.


Application form submitted to Medicines Management Information Team (medicines.management@hscni.net)
Application reviewed for suitability by Medicines Management Information Team
Consult Regional Pharmaceutical Procurement Service for impact on relevant contracts
Consult relevant expert group if applicable
Application rejected
Application accepted
Response to Applicant
Medicines Management Information Team to revise wording for inclusion in relevant therapeutic chapter(s) of Northern Ireland Formulary
Revised therapeutic chapter to be sent to Northern Ireland Formulary Editorial Group for final approval
Revised therapeutic chapter to be tabled at Medicines Management Forum for approval
Medicines Management Information Team to inform requesting practitioner/HSC Trust/Pharmaceutical Industry Company of decision