



***Interface Pharmacist Network
Specialist Medicines***

Shared Care Guidelines

**Guidance on the development & maintenance of
shared care guidelines for amber listed
medicines**

June 2019

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SECTION 1

Introduction

The purpose of this document is to facilitate the systematic development of shared care guidelines for amber list specialist medicines in Northern Ireland.

A specialist medicine is classified amber when it is deemed suitable for prescribing responsibility to transfer from secondary to primary care. The transfer process is dependent on an agreement between the initiating specialist and the GP.

The aim of a shared care guideline is to optimise patient care. Objectives include to:

- Define the shared responsibilities of practitioners involved in the patient's care.
- Provide appropriate information to ensure patient safety.
- Ensure efficient use of resources and expertise.

The Interface Pharmacist Network Specialist Medicines (IPNSM) will be responsible for:

- Identifying and prioritising guideline development in conjunction with the Regional Group on Specialist Medicines.
- Co-ordinating the guideline development process.
- Managing the introduction of new shared care guidelines.

The Regional Group on Specialist Medicines will be responsible for overseeing the introduction of shared care guidelines within HSCNI.

SECTION 2

Forming a shared care guideline development group (SCGDG)

- A workable size for the SCGDG is 10 to 12 people.
- The SCGDG members should be drawn from different Trusts across Northern Ireland.
- All SCGDG members are expected to attend all meetings/ link in to virtual meetings/ engage in electronic correspondence and to have a commitment to guideline development.
- The key constituents of the SCGDG are:
 - The Chair
 - Professional members
 - Interface Pharmacist for Specialist Medicines – task co-ordinator.
- The composition of the SCGDG will vary according to the topic covered by the guideline.

2.1 Selecting the Chair

The Chair should have some expertise in co-ordinating groups of health care professionals. The Chair is usually expected to have a good understanding of the guideline topic and is therefore likely to be a clinician. On occasion, however, he or she may be someone with facilitative skills who is not an expert in the topic area. Although clinical knowledge is not essential, it is usually advantageous in understanding the scope of the guideline and discussions surrounding its content.

The IPNSM will approach suitable members of the group in order to find and agree a Chair.

2.2 Key roles and functions of the Chair

To facilitate the group process the Chair:

- Assists with the planning of the meetings.
- Ensures that the group has relevant information.
- Provides opportunities for all members to contribute to the discussions.
- Will reach a consensus decision where required.

In meetings the Chair:

- Has a directive role in steering the discussions according to the agenda.
- Keeps the group discussion unified and avoids the disruption of sub-conversations and dominance by some members.
- Encourages constructive debate, without forcing agreement.
- Terminates repetitive debate.
- Supports the IPNSM in coordination of the guideline development.

2.3 Professional members

Professional members should be representative of the clinical area the guideline covers. Professional members may include among others.

- Hospital specialist/ consultant.
- GP.
- HSCB Medical Advisor.
- Clinical pharmacist.
- Primary care pharmacist.
- Specialist nurse (Primary and secondary care).
- Practice nurse/ district nurse/ treatment room nurse.
- Other AHP.

2.4 Selecting professional members

The professional members should be representative of the clinical area the guideline covers.

Secondary care: members should be drawn from different Trusts across Northern Ireland by contacting recognised experts in the clinical field or seeking nominations through the Trust medical directors.

GP members should be nominated by NIGPC/LMC.

2.5 Key roles of professional members

SCGDG members are expected to:

- Contribute constructively to meetings and have good communication and team working skills; this should include commitment to the needs of service users.
- Use background knowledge and experience of the management of the topic being covered.
- Read all relevant documentation and make constructive comments and proposals at SCGDG meetings and in the interim.
- Use their own networks to augment their contribution to the group.

They are **not** expected to:

- Search for literature.
- Write the guideline.

The membership of the group will be finalised by the Chair and task co-ordinator. The make-up of the group should be examined to ensure sufficient representation has been achieved.

2.6 Interface pharmacist specialist medicines (IPSM)

The role of the IPSM will be to act as a task co-ordinator and will encompass the following:

- Seeking nominations for professional members including the appointment of a Chair.
- Forming the group.
- Organising meetings.
- Identifying reviewing and providing evidence/information.
- Providing administrative support.
- Writing up the guideline.
- Maintaining version control as appropriate.
- Facilitating consultation.
- Taking the final shared care guidelines to the Regional Group on Specialist Medicines for ratification.
- Disseminating and implementing of the shared care guidelines.

SECTION 3

Running a shared care guideline development group (SCGDG)

As Task Coordinator, the Interface Pharmacist Specialist Medicines (IPSM), in consultation with the Chair, has the following core responsibilities:

- Defining the remit of group.
- Seeking agreement regarding the running the group, e.g. by face-to-face meetings, video-linked meetings, or electronic correspondence.
- Setting meeting dates.
- Planning agenda items.
- Sending out papers.
- Keeping a record of all meetings.

As task co-ordinator, the IPSM in conjunction with the Chair, agrees an approach to the guideline development in advance of the first meeting. and discusses any initial issues for consideration.

Members should be invited to complete a declaration of interest form and return this to the Interface Pharmacist Specialist Medicines co-ordinating the SCGDG. (Appendix 5)

3.1 General principles

As the SCGDG is multidisciplinary, its members will bring with them different beliefs, values and experiences. It is important that all these perspectives are listened to and that each member has an equal voice in the process. It is important to check that the terminology members use is understood by all and that the group obtains clarification when needed. The Chair should ensure there is sufficient discussion to allow a range of possible approaches to be considered, whilst making sure the group remains focused on the guideline remit and the timescale of the project. Decision making methods used to come to a consensus should be documented by entering these into the SCGDG database as appropriate.

SECTION 4

Identification of evidence and information sources

4.1 Sources of information

It is important to ensure that the SCG development process is as thorough and unbiased as possible.

It is equally important to determine the best practice to be recommended and the best evidence to support the information in the shared care guidelines.

Sources of acceptable information should be evidence based and recognised within the NHS.

Suitable sources of information:

- Systematic reviews.
- Randomised controlled trials.
- Other shared care guidelines.
- Guidelines issued by professional bodies.
- NICE guidelines.
- Local practice guidelines.

Information less suitable for inclusion:

- Studies of weak design.
- Promotional literature.
- Editorials interpreting trial results.
- Representations or experiences of individuals.
- Commercial 'In confidence' material.

4.2 Documentation of evidence

All evidence or information considered by the SCG development group should be documented and recorded by the task co-ordinator.

SECTION 5

Writing a shared care guideline

5.1 Guideline structure

Arrange the information within the fixed template (Appendix 3) using the:

- standard titled sections, and
- create bold headings within these sections.

5.2 Presentation

Using lists

- Use a bulleted list rather than a numbered one, to avoid implying a ranking or preference.

Using tables and figures

- Tables need to be readily understood and have a clear informative title.
- Limit footnotes unless essential.
- Number tables sequentially

Using abbreviations

- If it is thought that general readers will be familiar with an abbreviation, use it throughout after defining at first use.

Font

- Use Arial 14 where possible.
- Limit bold print to section titles and headings within sections (See template). In text, apply bold only to agreed key statements.

5.3 Producing the draft document

See also Appendix 3; Figures i, ii, and iii for information on the specific stages involved.

Generally:

- Produce an initial draft document prior to the groups' first meeting in agreement with the Chair.
- Distribute this document to the development group for comment in advance of the first meeting as an initial starting point in the development process, to initiate discussion, and clarify relevant areas etc.
- Record any comments or recommendations made by the development group in response.
- Discuss with the group if there is a need to seek opinions or comments from outside the group.
- Review and resolve these comments with the group.
- Distribute the amended draft to the group for any further clarification and comment, continuing this process until the group are in agreement to proceed to consultation.
- In some instances the Chair may need to agree a consensus decision.
- Once agreed, distribute to the group together with the collated and resolved comments.

SECTION 6

6.1 The consultation process

The 'draft for consultation' will be circulated by IPNSM via email to HSCNI. An established distribution list to reach stakeholders is held and maintained by IPNSM. The email will request recipients to cascade onward throughout their organisation as appropriate.

Recipients include:

HSC Board	Chief Executive Director of Commissioning Director of Integrated Care Assistant Director of Pharmacy and Medicines Management Assistant Director General Medical Services
Public Health Agency	Director of Public Health/Medical Director Director of Nursing and Allied Health Professionals
HSC Trusts	Chief Executives Medical Directors: for cascade to relevant staff Directors of Acute Services / Clinical Services Directors of Nursing: for cascade to relevant staff Chair of Drug & Therapeutics Committee Directors of Pharmaceutical Services/Head of Pharmacy and Medicines Management Interface Pharmacists Specialist Medicines
Other	Chief Executive, Regulation & Quality Improvement Authority Hospices LMC Chair PCCNI Chair PSNI Chief Executive GPCNI Chair UCA Chair ICPs

The standard consultation period is six weeks, or as agreed with the Chair of the development group.

6.2 Principles of responding to comments

6.2.1 Recording comments

All comments received should be entered into a database. A report will be produced containing the following information:

- Commentator – name of organisation/body/person submitting comments.
- Section of guideline – highlighting which section comment relates to.
- Comments – specific comment (without editing).
- Response – for recording agreed outcome.

It may be necessary to request additional information from the commentator in order to assess the comment.

6.2.2 Evaluating and dealing with comments

- Review and resolve comments received with the group.
- Discuss with the group if there is a need to seek opinions from outside the group in order to resolve.
- Distribute the amended draft to the group for any further clarification and comment, continuing this process until the group are in agreement.
- In some instances, the Chair may need to agree a consensus decision.
- Once agreed, distribute to the group together with all collated and resolved comments.

6.2.3 Responding to comments

The following should be taken into account when responding to comments.

- Each comment should be acknowledged and answered as fully and as factually as possible. Some comments may be presented generally but should still be noted.
- If changes are made to the SCG, this should be made clear in the response.
- If no changes have been made, a full explanation should be given as to why it was not thought necessary.
- Comments made on draft guidelines:
 - Responses and changes must be made with the agreement of the whole SCGDG.
 - Any subsequent changes to guideline documents need to be reflected in each version and an audit trail of changes must be maintained.

6.3 Editing and final check prior to publication

The IPSM will edit the SCG document to ensure that:

- The style and format are according to the standard.
- The information is unambiguous.
- The information is clear and appropriate for the intended audience.

6.4 Signing off the guideline

Once the consultation has been completed and comments addressed, the documents are returned to the SCGDG to be signed off.

SECTION 7

The final document

The final, agreed document should be tabled as a full agenda item of the Regional Group of Specialist Medicines and then ratified. The purpose of this is to give the final endorsement of the document prior to the final publication and distribution.

A summary document covering any main issues of note in the development process should be provided.

The document should then be published on the IPNSM website and then throughout the HSCNI via the established distribution list (section 6.1 refers).

SECTION 8

See also Appendix 3; ii and iii for information on the specific stages involved.

Generally:

Updating guidelines and correcting errors

8.1 Scheduled review of existing SCGs (to be read in conjunction with Figure 2 and/or Figure 3).

- IPNSM reviews content against current information sources.
- In conjunction with the existing Chair of SCGDG agree if an update is required or not.
- If an update is not required notify RGSM and update version control and review date.

If an update is required:

- Invite members of the original SCGDG to join the review group for continuity.
- Invite new members if necessary.
- Aim for the same mix of professionals as the original group.
- Establish the continued need for a SCG e.g. is the drug still used, or would a GP letter/info sheet be more appropriate.
- Follow the development process used originally although electronic communication may be possible depending on the complexity of the process.
- Identify any major changes since the original publication
- Agree with the Chair, the scope of the review to be undertaken i.e. light touch /focused review.

8.2 Prompted review: updating guidelines before a scheduled review (to be read in conjunction with Figure 3)

The responsibility for updating the guideline will rest with the IPNSM. Reasons for a prompted review include emerging pharmacovigilance, changes in monitoring, or significant updates to related guidance, e.g. NICE.

In considering the update required:

- IPNSM consider if the change effects/impacts the shared care arrangements.
- IPNSM consult with the original SCGDG and if necessary the Regional Group on Specialist Medicines.
- SCGDG decide the scope of the update.

The update process options may include:

- Update SCG with no consultation (minor change).
- Focused discussion with specialists on changes to the SCG (limited review).
- Full consultation (full review).

8.3 Correcting errors

Corrections or changes will be made when:

- An error undermines the conclusions on which a recommendation has been based.
- An error may result in harm to patients.

8.3.1 Issuing a correction

- The guideline development group will consider the proposed error.
- If no error is considered to have been made this will be communicated to the individual or organisation who reported it.
- If a correction is to be made stakeholders will be notified either by the website only, or in writing and through the website. The Chair will decide which is more appropriate based on the nature and significance of the error.
- The web version will be corrected and this will be highlighted on the relevant first page.

APPENDICES

Appendix 1 Standard letter of invitation



Name
Address
Address
Address

Date

Dear <name>

Re: Development of Shared Care Guideline for <drug>

I am chairing a Group to develop of a Shared Care Guideline (SCG) for <drug> in the treatment of <condition> on behalf of the Interface Pharmacist Network Specialist Medicines (IPNSM) and the Regional Group on Specialist Medicines (HSCB).

A SCG is intended to detail the respective clinical responsibilities of the Specialist and the GP when Amber list medicines are prescribed by the GP on the recommendation of a specialist.

I would be grateful if you would nominate a suitable specialist in your organisation to participate in the guideline development,

An overview of the development process used is available on the IPNSM website (www.ipnsm.hscni.net) for your information.

Please do not hesitate to contact me if you would like to discuss this request further.

Yours sincerely,

Appendix 2 Comments sheet

Comments sheet for: _____

SCG section	Comments
Introduction	
Hospital specialist responsibilities	
GP responsibilities	
Adverse effects and contraindications	
Drug interactions	
Communication	
Footnotes	

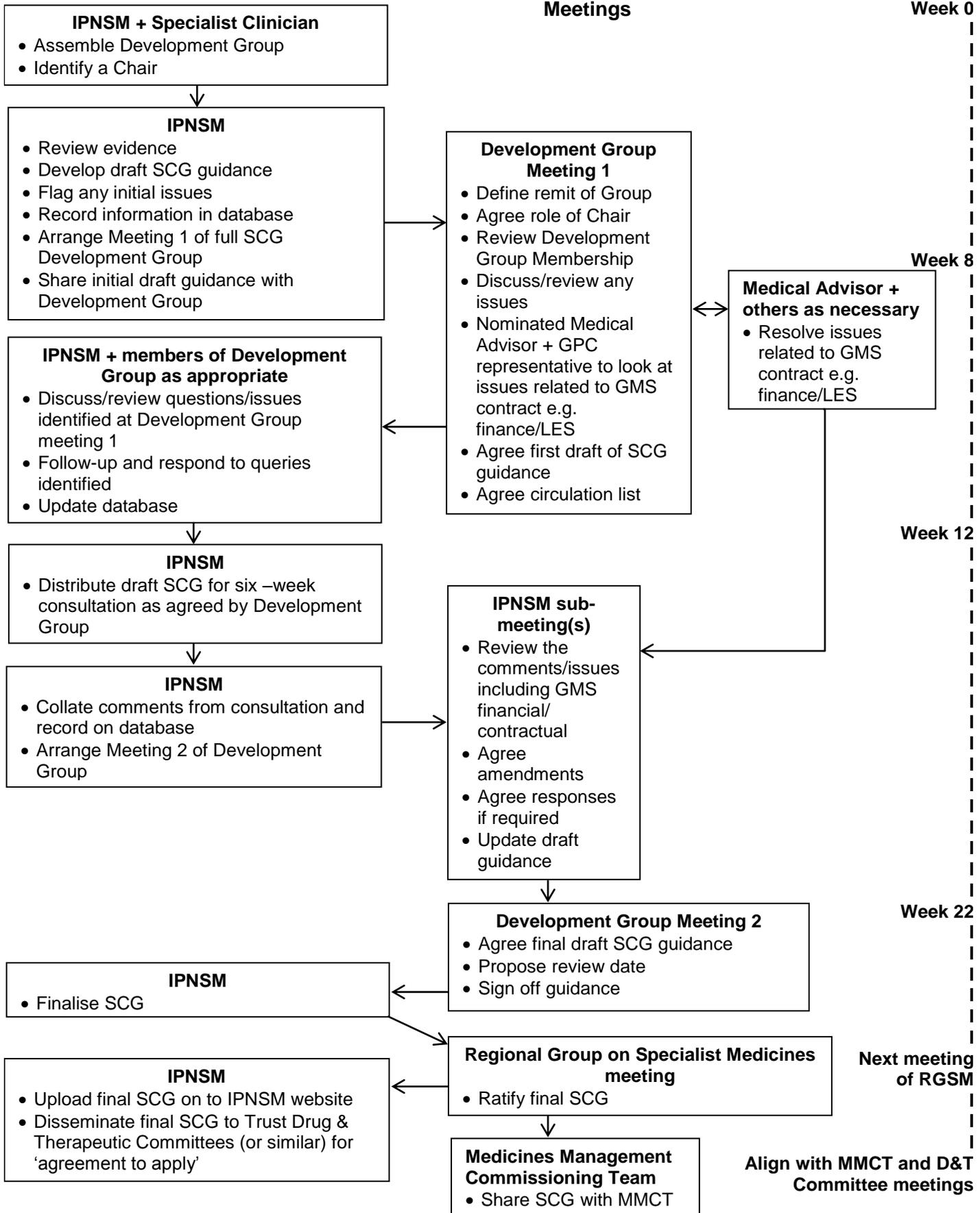
Name:

Contact details:

Appendix 3i Process Flowchart

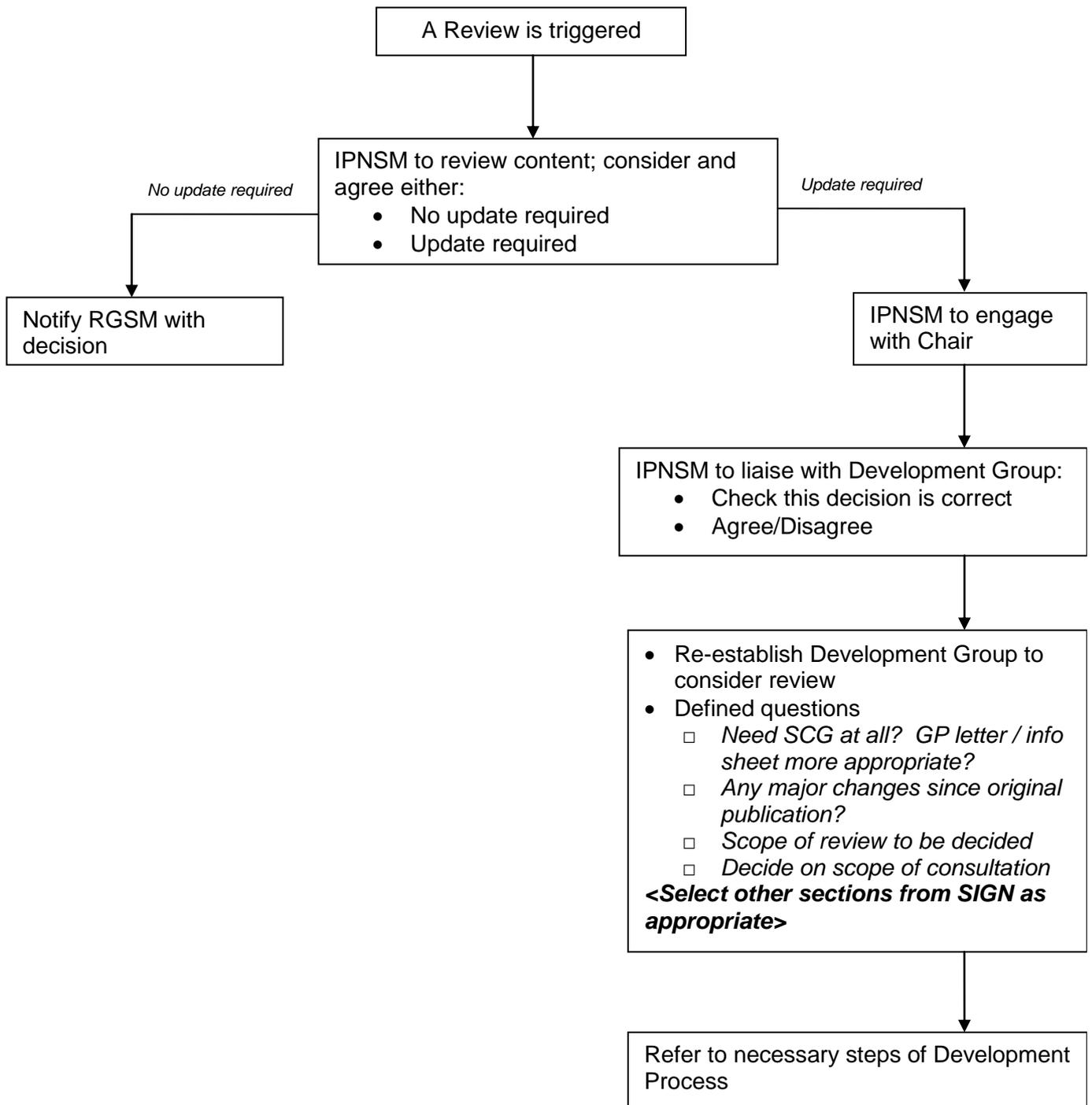
Process for the development of Shared Care Guidelines (SCGs) for amber medicines

Action/Responsibilities



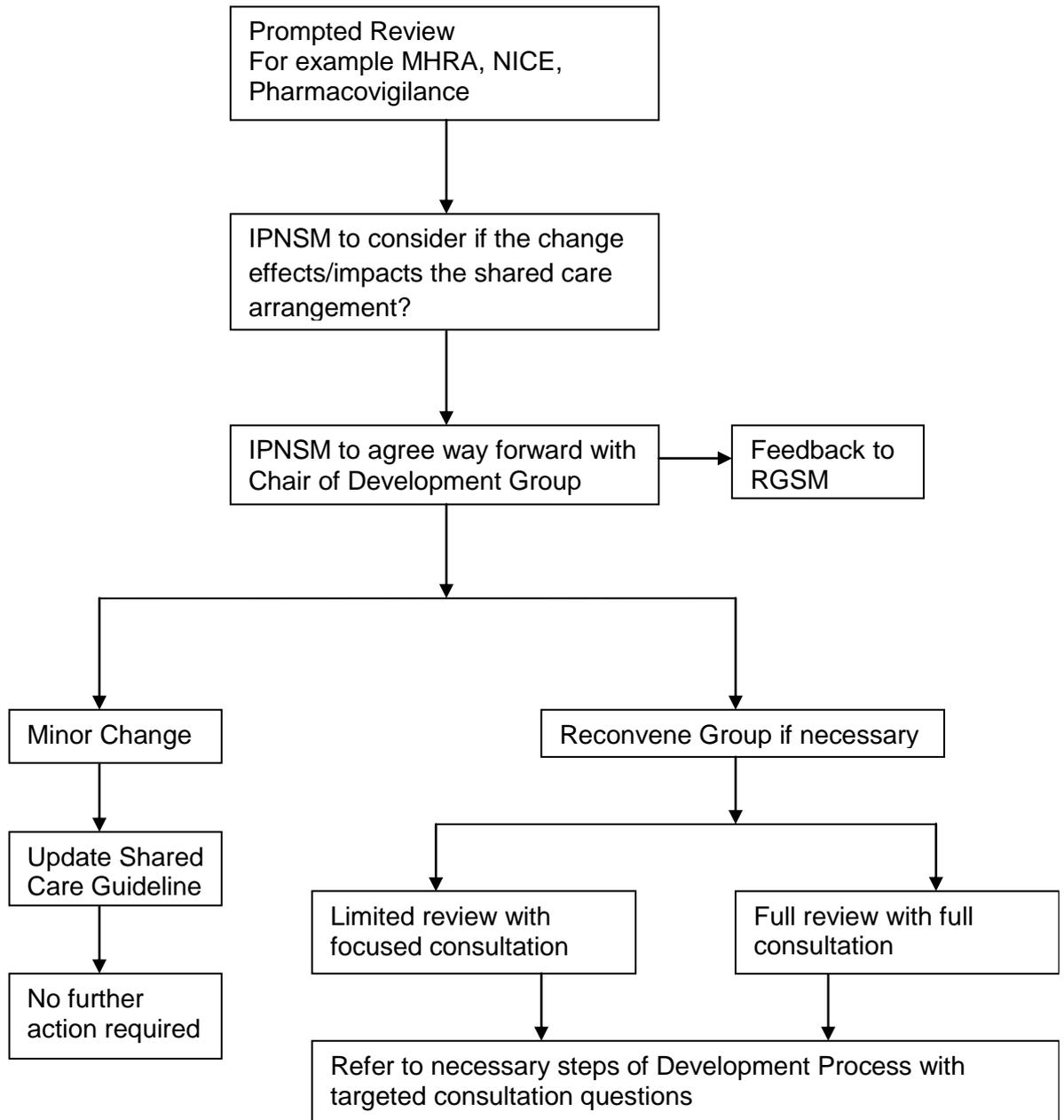
Appendix 3ii Process Flowchart

Process for Scheduled Review of Shared Care Guideline

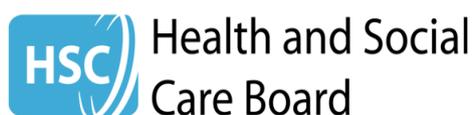


Appendix 3iii Process Flowchart

Process for Prompted Review of Shared Care Guideline



Appendix 4 Declaration of Interest Form



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, 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 possible 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 £50 (this figure is for guidance purposes)	

Name:

Employing organisation:

Signed:

For the year to date:

Return to: