SECTION 7: GUIDANCE ON THE PRODUCTION OF GUIDELINES AND PROTOCOLS INVOLVING MEDICINES

INTRODUCTION

This document aims to set out the processes involved in the preparation and ratification of therapeutic guidelines and protocols involving medicines intended for use by healthcare professionals within NHS Greater Glasgow and Clyde.

APPROVAL OF THERAPEUTIC GUIDELINES AND PROTOCOLS

Only guidelines that fulfil specific criteria will be presented for a formal Area Drugs and Therapeutics Committee (ADTC) review and ratification process. Guidelines will be reviewed by the Medicines Utilisation and Prescriber Education (MU&PE) Subcommittee which will have devolved responsibility to approve these on behalf of ADTC.

Not all protocols and guidelines require individual review by the MU&PE subcommittee, and the criteria at appendix 1 indicate those that will be reviewed. The purpose of the ADTC review is:

- To confirm that all appropriate stakeholders have been fully consulted
- To ensure that any implications for service delivery have been considered.
- To ensure that any significant impact on prescribing and workload in Primary Care or Secondary care has been considered.
- To ensure that any potentially significant cost or service implications are highlighted to the Prescribing Management Group.
- To facilitate the publication of the policy or protocol on to the ADTC website as appropriate.
- To endorse the use of specific disease management guidelines for use in NHSGGC

In certain situations ADTC may also commission the production of guidelines or protocols in order to define the circumstances in which certain drugs may be used.

All other NHSGGC medicines-related guidelines and protocols not fulfilling the criteria in appendix 1 should be reviewed and approved for use within the appropriate directorate by its senior clinical / management team. However, there will be an expectation that guideline groups will follow a number of principles set down by ADTC.

These principles are:

1. Guidelines and protocols should conform to the Greater Glasgow and Clyde Policy Development Framework.
2. There should be a clear description of the process for development of the guideline, the membership of the group involved and those consulted, together with any relevant 'declarations of interest'.
3. Guideline development groups should ensure that they have included a pharmacist and representation from all other relevant healthcare professionals groups.
4. All appropriate stakeholders must be fully consulted.
5. Consultation should take place throughout Glasgow and Clyde, where appropriate to ensure that the guideline is applicable across the Health Board area.
6. Where the therapeutic protocol or policy has significant implications for Primary Care, a representative sample of general practitioners should be involved in the development group. For such guidelines, the Local Medical Committee and the Primary Care Medicines Management team should be consulted for advice.
7. Consideration should be given to the involvement of patients or their support groups where appropriate.
8. All medicines included in NHSGGC therapeutic guidelines and protocols must already be included in the Glasgow and Clyde Formulary. There may be exceptions to this in the case of guidelines or protocols that incorporate the use of unlicensed medicines. Unlicensed medicines are not currently included in the Formulary.

9. Clinical specialists involved in the production of the guideline or protocol will be responsible for ensuring that the content is accurate and up-to-date and is based on current published evidence or best practice.
10. The guideline must give full details of the individuals involved in its production
11. The guideline must contain a date of preparation and a date of review.
12. Consideration should be given on how best to facilitate access to the guideline e.g. posting on the appropriate section of the Staff Intranet.

INCLUSION OF GUIDELINES OR PROTOCOLS IN THE GLASGOW AND CLYDE THERAPEUTICS HANDBOOK

In some instances it may be appropriate for a protocol or guideline to be included in the NHSGGC Therapeutics Handbook (Therapeutics-A Handbook for Prescribers). The Handbook is intended to be a reference source for prescribers in Acute Hospitals within Glasgow and Clyde. It is intended for use by prescribers requiring prescribing advice in the acute clinical situation. All guidelines included in the handbook must be agreed for use across all acute sites within Glasgow and Clyde. Criteria for inclusion of guidelines in the handbook are available from the Editorial Group. The Prescribing handbook Editorial Group will review all guidelines for suitability before they are approved for inclusion.

SUBMITTING A NEW GUIDELINE OR PROTOCOL FOR APPROVAL BY ADTC

The "Request for a protocol or Guideline to Reviewed by ADTC" form (Appendix 2) should be submitted to ADTC with all protocols or guidelines. The purpose of this form is to ensure that all information required for the ADTC and its subcommittee to make an informed decision about the protocol is available. The form includes a section requesting declarations of interest to be completed by the chair of the group. This is essential in order to ensure that the process is transparent and not open to challenge about bias. In addition, the "Approvals Cover Sheet" of the NHSGGC Policy Development Framework (appendix 1 of the framework) should also be submitted. All guidelines for ADTC review should be submitted to the ADTC secretariat at the address in appendix 3.

APPENDIX 1: CRITERIA FOR THERAPEUTIC PROTOCOLS/ GUIDELINES REFERRAL TO ADTC

Guidelines fulfilling **one or more** of the following criteria should be referred for review by ADTC.

1. The guideline or protocol has clinical implications for multiple directorates within Acute and for Primary Care.
2. There are significant new cost implications beyond a single directorate or speciality.
3. There are significant new service implications beyond a single directorate or speciality.
4. The guideline has been produced by a Managed Clinical Network
5. The protocol or policy includes non-Formulary medicines.

Where there is uncertainty about whether the policy or guideline fits the above criteria the guideline group may contact the Lead Pharmacist, Medicines Information or the Chair of ADTC for specific advice.

APPENDIX 2:

AREA DRUG & THERAPEUTICS COMMITTEE

REQUEST FOR A PROTOCOL OR GUIDELINE TO BE REVIEWED BY THE AREA DRUGS AND THERAPEUTICS COMMITTEE (ADTC)

SECTION 1: DETAILS OF THE PROTOCOL/GUIDELINE

NAME OF THE PROTOCOL/GUIDELINES:

SECTION 2: DETAILS OF THOSE INVOLVED

Was the protocol developed by a specialist interest group or Managed Clinical Network? If yes, please specify	**YES/NO**
If the protocol was not developed by an MCN? Did the group include members from across NHSGGC? *(Please list members of the group below or attach a list to this application)*	**YES/NO**
Have all stakeholders been fully consulted? *(Please give details)*	**YES/NO**

Protocol or guideline review group member	
NAME	**STATUS**

SECTION 3: IMPLICATIONS FOR PRIMARY CARE (ACUTE PROTOCOLS)

Are there any implications for prescribing practices or resources in Primary Care?	**YES/NO**
Have General practitioners been fully consulted? *(Please give details)*	**YES/NO**

SECTION 4: COSTS

Are there any cost implications associated with the introduction of this protocol or guideline (e.g. increased prescribing costs)? If yes, please detailS	**YES/NO**
Are there any service implications associated with the use of the drug therapy (e.g. diagnostic tests, monitoring, additional drug therapy etc)? If yes, please detail	**YES/NO**

SECTION 5: DECLARATION OF INTERESTS

APPENDIX 3: CONTACT DETAILS FOR RELEVANT ADTC MEMBERS

Chair of ADTC
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