GUIDANCE ON THE PRODUCTION OF GUIDELINES AND PROTOCOLS INVOLVING MEDICINES

Introduction

This document aims to set out the processes involved in preparation, ratification and review of therapeutic guidelines and protocols involving medicines intended for use by healthcare professionals within NHS Lanarkshire (NHSL).

Approval of therapeutic guidelines and protocols

Guidelines that fulfil specific criteria in **appendix 1** should be presented for formal ADTC review and approval.

The purpose of 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 board
- To facilitate the publication of the guideline on NHSL guideline website
- To encourage the use of specific disease management guidelines for use in NHS Lanarkshire

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

All other NHSL medicine related guidelines and protocols not fulfilling the criteria in appendix 1 should be reviewed and approved for use within the appropriate directorates by its senior clinical/management teams. However, the groups developing the guidelines will be expected to follow a number of principles set down by ADTC.

These principles are:

1. Guidelines and protocols should conform to the NHSL policy development framework
2. There should be a clear description of the process for development of 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 professional groups

4. All appropriate stakeholders must be fully consulted
5. Consultation should take place throughout NHSL, as appropriate to ensure that the guideline is applicable across the health board area
6. Where the therapeutic protocol has significant implication for primary care, representation from primary care should be involved in the development group
7. Consideration should be given to the involvement of patients or their support groups where appropriate
8. Clinical specialists involved in the production of the guideline or protocol will be responsible for ensuring that the content is accurate, up to date and is based on current published evidence or best practice
9. The guideline must give full details of the individuals involved in its production
10. The guideline must contain a date of preparation and a date of review
11. Consideration should be given on how best to facilitate access to the guideline e.g. posting on NHSL guideline website

Submitting a new guideline or protocol for approval by ADTC

The form in **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 to make an informed decision about the protocol is available.

All the guidelines for ADTC review should be submitted to ADTC by e mail:

E Mail: adtc@lanarkshire.scot.nhs.uk

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 clinical guideline involves **use of medicine(s)** and has clinical implications for **multiple** directorates within Acute **and/or** is expected to be used across Acute **and** Primary Care
2. There are significant new cost implications beyond a single Acute Service and for Primary Care
3. There are significant new service implications beyond a single Acute Service and for Primary Care
4. The clinical guideline has been produced by a Managed Clinical Network
5. The clinical guideline includes non-formulary medicines
6. Clinical guidelines developed for new medicines specifically at the request of Area Drugs and Therapeutics Committee or its subcommittee.

Where there is uncertainty about the guideline needing ADTC approval, advice should be sought from chair of ADTC

Appendix 2

AREA DRUG and THERAPEUTICS COMMITTEE
REQUEST FOR MEDICINE RELATED PROTOCOL OR GUIDELINE TO BE REVIEWED BY THE ADTC

SECTION 1: DETAILS OF PROTOCOL/GUIDELINE

NAME OF THE PROTOCOL/GUIDELINE and MEDICINE INCLUDED

SECTION 2: DETAILS OF THOSE INVOLVED

Was the protocol developed by a specialist interest group or MCN? If yes, please specify	Yes/No
Did the group include members from across NHSL (if protocol not developed by MCN)? (Please list members of the group or attach a list)	Yes/No
Have all stakeholders been fully consulted? (please give details)	Yes/No

SECTION 3: IMPLICATIONS FOR PRIMARY CARE (ACUTE PROTOCOLS)

Are there any implications for prescribing practices or resources in primary care (e.g. additional monitoring, etc.)	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 give 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 give details	Yes/No

SECTION 5: DECLARATION OF INTERESTS

Has any conflict of interest been recorded on NHSL e portal? http://vsv-346:81/Default.aspx Guidance on declaration of interest : http://firstport2/staff-support/gifts-hospitality-staff-interest/default.aspx	Yes/No

Form Submitted by:	Name:
	Date: