



## In this issue ...

- Introducing the Lothian Prescribing Bulletin
- The Scottish Medicines Consortium and New Drugs
- PROGRESS in the Treatment of Stroke
- Withdrawal of nefazodone ( Dutonin<sup>®</sup> )

First Issue

## Introducing the Lothian Prescribing Bulletin

Welcome to the first edition of the Lothian Prescribing Bulletin (LPB).

### Who is it for?

The LPB is for all doctors, nurses and pharmacists in Lothian and all those interested in clinically effective and cost effective prescribing in primary and secondary care.

### Why should you read it?

The LPB will provide clear guidance and support across Lothian about:

- Current prescribing issues
- Local prescribing policies
- New drugs and Scottish Medicines Consortium (SMC) recommendations
- The latest Lothian Joint Formulary (LJF) recommendations and developments
- Important new evidence from drug trials

### Why have we produced the LPB?

We aim to promote a consistent approach to prescribing issues across Lothian. As many prescribing issues become increasingly complex, we are aware of a need to improve communication between primary and secondary care. We aim to build on the success and expertise of the "purple bulletin" (primary care Prescribing bulletin) and extend its remit and authorship to cover all Trusts in Lothian.

The LJF is now well established. A joint formulary needs joint implementation and this bulletin will inform prescribers in hospitals and general practice about key messages and changes to the LJF.

The development of the SMC has led to changes in our process for the introduction of new drugs into clinical practice. This bulletin will provide information about SMC recommendations. The new process for introducing new drugs into clinical practice in Lothian is explained overleaf.

### Who is producing this bulletin?

The editorial team (see back page) have a wide range of experience in producing bulletins and newsletters and are actively involved in many aspects of prescribing in Lothian, including the LJF. We intend to invite contributions to the LPB from our readers. We would also welcome suggestions for articles. The LPB is your bulletin, tell us what you want - you can contact the LPB editorial team by email at [ljf@lhb.scot.nhs.uk](mailto:ljf@lhb.scot.nhs.uk)

### How much will it cost me?

Nothing - it's free! Look out for LPB every 2 months.

### What does the Area Drug and Therapeutics Committee (ADTC) think of this new initiative?

Professor David Webb (Chairman, ADTC) writes:

"The ADTC is keen to support initiatives that promote safe and cost effective prescribing, to the benefit of patients in Lothian. The creation of the LJF, both in paper and electronic forms, and now of the LPB are important developments we believe will support seamless prescribing across the interface between primary and secondary care. In addition, we expect the LPB will allow the ADTC to improve communication of its work, and of developments nationally, in support of quality prescribing and to receive valuable feedback from prescribers."

# The Scottish Medicines Consortium and New Drugs

Mr Malcolm Chisholm, Health Minister, stated in the Scottish Parliament (3 January 2003) that:

**“NHS Scotland is expected to take account of advice and evidence from bodies such as the Health Technology Board and the Scottish Medicines Consortium and ensure that recommended drugs or treatments are made available to meet clinical need.”**

In line with this statement and following discussion at the Area Drug and Therapeutics Committee (ADTC), and with subsequent support from Trust Medical Directors and Chief Executives in Lothian, it has been agreed that the Scottish Medicines Consortium (SMC) recommendations will be accepted.

## **New process for the introduction of new drugs into clinical practice in Lothian**

A new process has been developed for the introduction of new drugs into clinical practice in Lothian following the formation of the SMC. The SMC evaluates and makes recommendations about all new drugs for NHS Scotland. During 2002 the SMC provided recommendations on 21 drugs:

- 5 recommended for general use
- 11 for restricted use
- 5 not recommended for use

The development of the SMC necessitated a review of our existing system for the management of the introduction of new drugs into clinical practice. Accordingly, the Lothian Drug Evaluation Panel has ceased to evaluate the clinical and cost effectiveness of new drugs as this work is now being undertaken by the SMC. The Lothian Formulary Committee, in consultation with local clinicians, will establish the place in therapy of new drugs.

## **What is the new process?**

There is always anxiety around the funding of new medicines. Funding will now happen in parallel with the agreement on appropriate use. Therefore, when the formulary status of a new drug is known the funding position will have been clarified.

It is important that the Formulary Committee establish, in collaboration with clinicians and pharmacists:

- how the drug will be used
- the number of patients likely to be treated
- the patient group to be treated
- a relevant shared care protocol if appropriate
- the resource implications

A new process has been established to collect this information as quickly as possible and thereby speed up the implementation of SMC recommendations (see chart on opposite page). It is proposed that funding for new drugs will be anticipated and established in Trust budgets at the beginning of each financial year with a contingency fund held for in-year developments. These will inevitably be estimates that will have to be refined with the use of the drug over time. The Medicines Resource Group has been set up in NHS Lothian to audit drug costs. This simplifies and clarifies the process so that SMC recommendations can be implemented with the minimum of delay.

This is a considerable change from the previous medicines management practice in Lothian and we believe it is a significant step forward in abolishing postcode prescribing.

## **How will prescribers know?**

This bulletin will keep prescribers informed and information and advice will also be posted on the LJF website - [www.ljf.scot.nhs.uk](http://www.ljf.scot.nhs.uk). The SMC also has a website - [www.scottishmedicines.org.uk](http://www.scottishmedicines.org.uk).

## **In the real world ...**

You are interested in prescribing a new preparation and you are unsure of its status, what should you do?

Check the LJF website and the LPB - has it been added to the LJF? All SMC recommended drugs are considered by local clinicians and then the Formulary Committee. A summary of Formulary Committee recommendations will be posted on the LJF website - [www.ljf.scot.nhs.uk](http://www.ljf.scot.nhs.uk).

## **Key messages:**

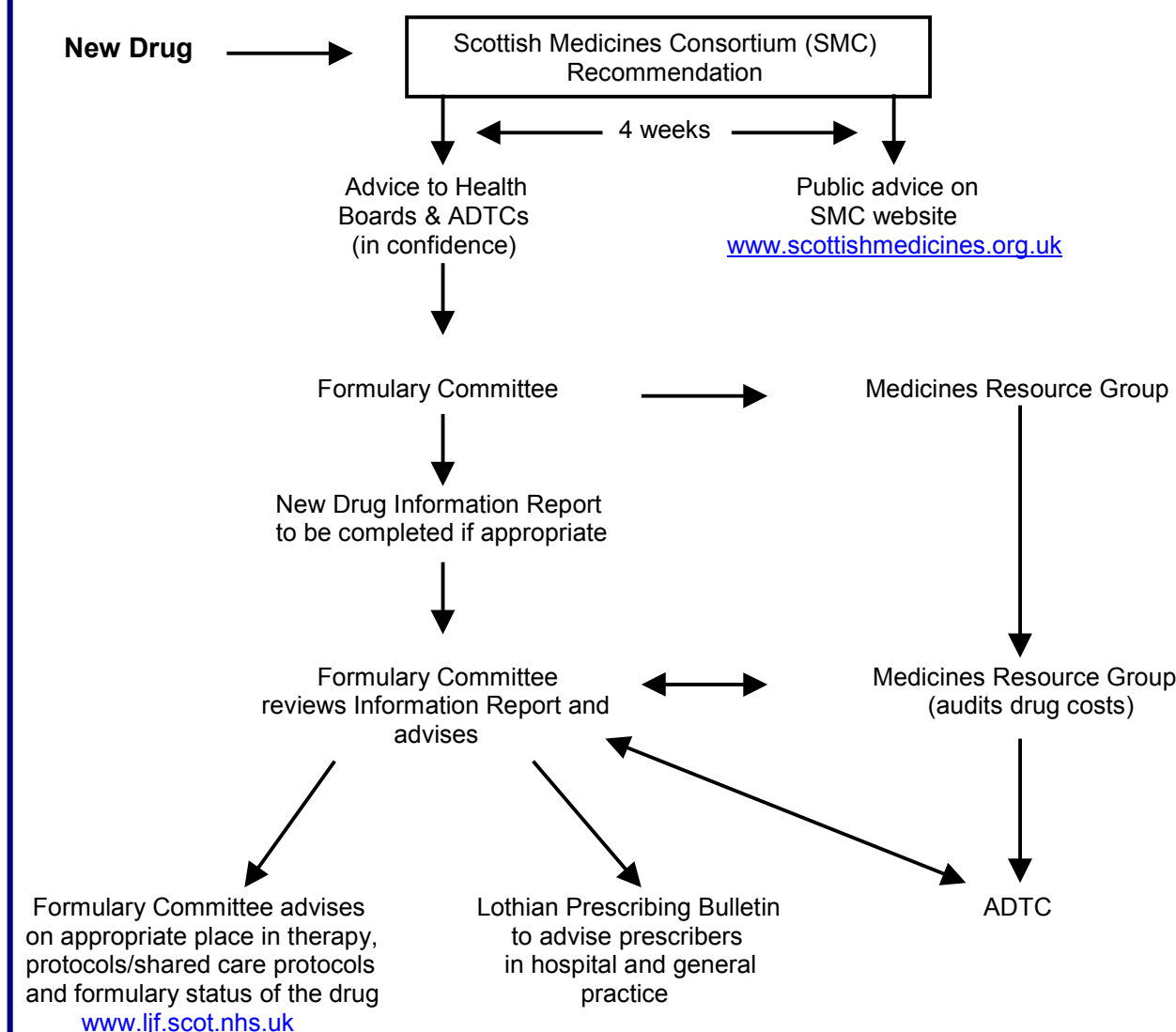


**New drugs can be prescribed after they have been recommended by SMC and been considered by the Formulary Committee.**



**When drugs are not recommended for use by SMC they should not be prescribed in Lothian.**

## NEW DRUG APPROVAL in Lothian



This bulletin will inform you of SMC recommendations. At this time we are able to tell you about the drugs that are not recommended. For further information please see the website [www.scottishmedicines.org.uk](http://www.scottishmedicines.org.uk).

Product and Formulation	Indication	SMC Recommendation
anakinra (Kineret <sup>®</sup> ) injection	Rheumatoid arthritis	NOT RECOMMENDED
biphasic insulin aspart (Novomix <sup>®</sup> ) injection	Diabetes	NOT RECOMMENDED
calcipotriol & betamethasone (Dovobet <sup>®</sup> ) ointment	Psoriasis	NOT RECOMMENDED
drospirenone 3mg ethinylestradiol 30mcg (Yasmin <sup>®</sup> ) tablets	Combined oral contraceptive	NOT RECOMMENDED
omega-3-acid ethyl esters (Omacor <sup>®</sup> ) capsules	Hypertriglyceridaemia	NOT RECOMMENDED
parecoxib (Dynastat <sup>®</sup> ) injection	Surgical pain	NOT RECOMMENDED
zoledronic acid (Zometa <sup>®</sup> ) infusion	Bone metastases	NOT RECOMMENDED

# PROGRESS in the Treatment of Stroke

## What do we know?

Hypertension is a major risk factor for stroke in the Scottish population. However, there has been uncertainty about the efficacy and safety of giving antihypertensive drugs to patients with established stroke regardless of their hypertensive status.

Specific concerns have been raised about the dangers of reducing cerebral perfusion. The PROGRESS trial was designed to determine the effects of lowering blood pressure in this group of patients whether they were diagnosed as hypertensive or not<sup>1</sup>.

## The PROGRESS Trial

*Design* - randomised placebo-controlled trial

*Subjects* - 6,105 patients with a history of stroke or transient ischaemic attack

*Treatment* - ACE inhibitor perindopril, with the addition of the diuretic indapamide (added at the discretion of the physician) versus placebo

*Follow-up* - average 4 years

*Primary outcome measure* - total stroke (fatal or non-fatal)

## Results

Active treatment reduced blood pressure by 9/4mmHg (perindopril-only, 5/3mmHg; perindopril-indapamide 12/5mmHg). There was a highly significant 28% relative risk reduction of stroke for those assigned active treatment (10% v 14%). Active treatment also reduced the risk of total major vascular events by 26%. The reductions in the risk of stroke were similar in all subgroups irrespective of initial blood pressure. While the perindopril-indapamide combination therapy reduced stroke risk by 43%, perindopril-only therapy produced no discernible reduction in stroke.



## Key messages:

- Patients with established cerebrovascular disease are at high risk of further events.
- PROGRESS removes any doubts that blood pressure lowering might be generally harmful in this group and, conversely, indicates the extent of the clinical benefits, even in patients who are considered normotensive.
- The extent of the benefit was closely related to the reduction in blood pressure achieved by the treatment pointing to the possibility that it relates to pressure reduction per se rather than specific to individual drug classes.
- Consider antihypertensive therapy for all patients with a history of stroke or transient ischaemic attack.
- The trial supports the benefits of the combination of a diuretic and an ACE inhibitor.
- The Formulary Committee believes that there is little compelling evidence to suggest that the benefits are anything other than a class effect of the diuretic-ACE inhibitor combination.

## LJF recommendations:

**bendroflumethiazide** (bendrofluazide) first choice thiazide diuretic  
**enalapril** first choice ACE inhibitor

## Reference:

1. PROGRESS Collaborative Group. Lancet 2001; 358: 1033-41

## Withdrawal of nefazodone (Dutonin®)

Bristol-Myers Squibb recently announced their intention to stop producing the antidepressant nefazodone (Dutonin®). The stocks of nefazodone are expected to last until the end of March 2003. For patients who could now have their course of treatment stopped, the drug should not be withdrawn abruptly but the dose reduced gradually over 4 weeks, by weekly decrements. This slow withdrawal is recommended to avoid withdrawal reactions. In some cases, switching to an alternative antidepressant will be required. Advice on switching from nefazodone to other antidepressants was sent to all prescribers from Bristol-Myers Squibb at the end of January 2003.

## Next Issue ...

**The ALLHAT trial**  
Look out for a summary in the next edition of LPB.

**Correspondence address:**  
Medicines Management Team  
Stevenson House  
555 Gorgie Road  
Edinburgh  
EH11 3LG  
Tel: 0131-537-8573

## Editorial Team:

Dr David Crookes, Medicines Management Adviser  
Ms Anne Gilchrist, MMT Pharmacist  
Ms Sharon Hems, Formulary Pharmacist  
Ms Helen Jackson, MMT Co-ordinator  
Mr William John, Primary Care Pharmacist

Dr Simon Maxwell, Senior Lecturer in Clinical Pharmacology  
Ms Sandra McNaughton, Primary Care Pharmacy Co-ordinator  
Dr Philip Rutledge, Director of Medicines Management  
Dr Richard Williams, Prescribing Convener, GP Sub-Committee