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SIG Hot Topics

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16.30 – 18.30

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Patient Access to New Medicines



A Scottish perspective

This presentation...

**will describe the processes
in place in Scotland to
manage the introduction
of new medicines
with specific reference to
the Edinburgh region.**

Budgetary constraints – hard times!

- Decision making about medicines even more important in the challenging financial times ahead
- We must ensure that processes are in place to ensure fair and equitable allocation of resources



Managing the introduction of new medicines and their expenditure

National guidance...

NHS Lothian follows guidance set by the Scottish Medicines Consortium (SMC).

...linking to local systems

A Formulary Committee is in place in Lothian. Its role includes interpretation of SMC guidance for local implementation and assessing the associated costs.

The Formulary Committee places SMC recommendations into a local context within the Lothian Joint Formulary.

Scottish Medicines Consortium



Scottish Medicines Consortium - return to homepage

About SMC

SMC Advice

Submission Process

Public Involvement

Scottish Antimicrobial Prescribing Group



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What we do

The remit of the Scottish Medicines Consortium (SMC) is to provide advice to NHS Boards and their Area Drug and Therapeutics Committees (ADTCs) across Scotland about the clinical and cost-effectiveness of all newly licensed medicines, all new formulations of existing medicines and new indications for established products (licensed from January 2002). [Read more on what we do.](#)

SMC Advice

Latest Advice

- certolizumab pegol (Cimzia) Resubmission
- ethinylestradiol 30mcg and levonorgestrel 150mcg (Rigevidon)
- ethinylestradiol and desogestrel (Gedarel)

Submission Process

Latest news

Scottish Medicines Consortium

approved/ recommended for use in the NHS

- Regional Health Boards expected to make medicine (or equivalent) available

not approved / not recommended for use in the NHS

- Regional Health Boards expected to follow advice
- Health Boards can consider use in line with the 'Individual Patient Treatment Request' process

Medicines Accepted by SMC

Local (regional) ownership

- **Formulary Committee reviews medicine against other existing medicines available to treat the condition in question considering**
 - √ **Inclusion in local formulary**
 - √ **Overview of place in therapy**
 - √ **Treatment protocol**
 - √ **Resource and service implications**
- **Formulary Committee makes recommendation to Health Board**
- **Communication and implementation**

The Lothian Joint Formulary

...a formulary designed to provide guidance on first and second choice drugs, where appropriate, for the treatment of common conditions in the vast majority of patients.

The Lothian Joint Formulary

www.ljf.scot.nhs.uk



Lothian Joint Formulary - Microsoft Internet Explorer

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Lothian Joint Formulary

Welcome to **the Lothian Joint Formulary**.

Please click below to access the formularies:

Adult Formulary	Child Formulary	Minor Ailments Formulary	Nursing Formulary	Dental Formulary
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other links to:

- [Shared Care Protocols](#)
- [Support Material for the LJF wound section](#)
 - [LJF Dressing Choices table](#)
 - [LJF Dressing Selection Guide](#)
- [Guidelines for the Management of patients with Hypercholesterolaemia at risk of cardiovascular disease \(CVD\)](#)
 - [Summary of Lothian LIPID Guideline 2009](#)
- [Medicines for the doctor's bag - Guidance for the use of medicines in Lothian during normal working hours](#)
- [Adult Medical Emergencies Handbook \(4Mb\)](#)
- [Recommendations on NEW DRUGS from the LOTHIAN FORMULARY COMMITTEE \(FC\)](#)
- [Drugs NOT RECOMMENDED by the Scottish Medicines Consortium](#)
- [Formulary Committee Recommendations on unlicensed and off-label medicines \(FAF3\), and medicines not considered by SMC \(FAF2\).](#)
- [GPASS:- \(for GPASS users only\)](#)
- [GPP Packs - New choice answer sheets](#)

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Aims - The Lothian Joint Formulary

- ✓ promote safe, effective and economic prescribing
- ✓ reach agreement between primary and secondary care about which drugs should be prescribed
- ✓ promote a seamless approach to prescribing
- ✓ produce greater familiarity with a limited range of drugs
- ✓ encourage generic prescribing
- ✓ manage the introduction of new drugs
- ✓ avoid information overload
- ✓ provide a quality standard for prescribing in Lothian

New national directive - Individual Patient Treatment Requests

A new national directive

‘Introduction and Availability of Newly Licensed Medicines in the NHS in Scotland’ was published by the Scottish Government in May 2010.

Introduces the ‘Individual Patient Treatment Requests’ process, for medicines not recommended by Scottish Medicines Consortium (SMC).

http://www.sehd.scot.nhs.uk/mels/CEL2010_17.pdf - Microsoft Internet Explorer

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Healthcare Policy and Strategy Directorate
Quality Division


The Scottish Government

Dear Colleague

INTRODUCTION AND AVAILABILITY OF NEWLY LICENSED MEDICINES IN THE NHS IN SCOTLAND

Dear Colleague

This guidance sets out the policy framework with regard to the introduction and availability of newly licensed medicines in the NHS in Scotland which includes wider considerations such as the Pharmaceutical Price Regulation Scheme (PPRS) and Patient Access Schemes (PAS). It has been developed in consultation with key stakeholders and consolidates previous guidance issued under [HDL\(2003\)60](#) and [HDL\(2006\)29](#).

Purpose

The key purpose of this guidance is to provide a framework within which NHS Boards are expected to align their local policies regarding access to newly licensed medicines. The framework will provide a solid basis for the development of local policies and is designed to achieve a consistent approach to the introduction of newly licensed medicines across NHSScotland.

Scope

CEL 17 (2010)
17 May 2010

Addresses

For action
NHS Board Chief Executives
Special NHS Board Chief Executives
NHS Board Directors of Public Health
NHS Board Medical Directors
NHS Board Directors of Pharmacy
NHS Board Chairs of Area Drugs and Therapeutics Committees
NHS Board Exceptional Prescribing Leads
Regional Cancer Network Mangers
Regional Cancer Network Lead Clinicians
Regional Cancer Pharmacy Leads

For information
Chair, Scottish Medicines Consortium

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Aim of guidance

To provide a framework within which NHS Boards are expected to align their local policies regarding access to newly licensed medicines.

The framework will provide a solid basis for the development of local policies and is designed to achieve a consistent approach to the introduction of newly licensed medicines across NHSScotland.

New medicines in Scotland

- who decides what the NHS can provide?

Health Rights Information Scotland has worked with the Scottish Government Health Directorates to produce information that explains the process medicines go through before NHS staff in Scotland can routinely prescribe them. Several organisations are involved in approving a medicine for use and the role of each is described. The information is for the public and patients.



New medicines in Scotland

– who decides what the NHS can provide?

What is this factsheet about?

This factsheet explains the process that medicines go through before NHS doctors in Scotland can routinely prescribe them.

The person prescribing a medicine must make sure the patient knows how to use it safely. Medicines are usually prescribed by a doctor. In this factsheet, we use the word "doctor" to describe the person prescribing the medicine. The doctor is responsible for choosing the medicine used.

If you have questions about the medicines you have been prescribed or you wish to discuss any part of your NHS treatment, you can ask the doctor in charge of your care.

What happens before a medicine can be prescribed?

- In Scotland, a medicine usually has to have a licence (also known as a marketing authorisation) before it can be prescribed to treat people.
- A licence will only be granted if there is evidence from a clinical trial that the medicine is safe, of good quality, and

worked for those people taking part in the trial. Medicines are usually licensed for use in adults who have a particular illness or condition.

- As well as being licensed, a medicine usually needs to be recommended for use by the NHS in Scotland before it can be prescribed by your doctor.

Action for regional services

- Local processes are in the process of being revised, with an Individual Patient Treatment Request process for SMC not recommended medicines, and a non-formulary process (which will include SMC recommended but Lothian non-formulary medicines).
- This is a significant change to the current processes.

Any questions?

