TAYSIDE PRESCRIBER

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Local Implementation of National Advice on New Medicines

National advice on the use of new medicines is now provided by the Scottish Medicines Consortium (SMC). New medicines should not normally be prescribed until a recommendation for use has been issued by the SMC and considered locally. Refer to ADTC Supplement No.20 for advice in situations of compelling clinical need.

The Tayside New Medicines Implementation Panel (NMIP) will be established shortly. This Panel will have a remit to facilitate the implementation of national advice in relation to local practice and aims to issue local advice at the same time, or shortly after, the SMC publish national advice on their website (www.scottishmedicines.org.uk).

SMC Advice Issued in November 2002

Five recommendations covering the use of four medicines were issued by the SMC in November 2002. Brief information on these medicines is provided in this bulletin. In each case, the SMC statement is highlighted and followed by local points for consideration. The symbol H identifies products that should only be prescribed in secondary care.

Bexarotene (Targretin$^{\delta}$) – Cutaneous T-cell lymphoma (CTCL) **No.14/02**

- Bexarotene is an anti-neoplastic retinoid licensed to treat the skin manifestations of advanced stage CTCL in patients refractory to at least one systemic therapy.
- Bexarotene shows improved response rates, as assessed by the Composite Assessment of index lesion disease severity, in uncontrolled open studies.

Recommended for restricted use.
Bexarotene is recommended for use in Scotland as a second-line treatment for patients with advanced (stages IIb or III) CTCL. Bexarotene treatment should normally be initiated and supervised by haematologists, dermatologists or oncologists and used for patients who have proved refractory both to local skin directed therapy and to at least one systemic treatment.

Local points for consideration:

- Bexarotene is restricted to secondary care.
- Guidelines for the management of CTCL are under development by the British Association of Dermatologists and the UK Cutaneous Lymphoma Group

90% omega-3-acid ethyl esters (Omacor$^{\delta}$) – 2^{ndry} prevention post MI **No.15/02**
- hypertrigyceridaemia **No.16/02**

- Omacor capsules contain high concentrations of omega-3 polyunstaurated fatty acids (n-3 PUFAs). They are licensed for the treatment of endogenous hyertriglyceridaemia and as an adjuvant in secondary prevention post MI in addition to other standard therapy e.g. statins, antiplatelet drugs, beta-blockers, ACE inhibitors.
- Omacor shows significantly reduced cardiovascular death versus placebo when added to standard treatment < 3 months post MI.

Post MI

Acceptable for general use as an additional treatment for the secondary prevention of myocardial infarction.
Whilst cost-effectiveness appears to be within generally acceptable limits, NHS Boards will recognise that there are now a number of established interventions for this indication. The priority given to this agent needs to be considered alongside the implementation of other effective approaches to secondary prevention of cardiovascular disease, always keeping in mind alternative dietary methods of obtaining fish oil supplementation.

Hypertriglyceridaemia

Not recommended for use.
This is based on the lack of long-term data to indicate that reductions in triglyceride levels provide real benefit in terms of reducing cardiovascular events, on a lack of evidence of increased patient acceptability of the product, and lack of a pharmacoeconomic case for the drug.

Local points for consideration:

- Evidence to support the use of Omacor post MI is based on an Italian population consuming a typical Mediterranean diet and receiving low levels of cholesterol-lowering medication and, therefore, may not be applicable to a Scottish population.
- SIGN Guideline No. 57 'Cardiac rehabilitation' recommends an increased intake of n-PUFAs in conjunction with other dietary and lifestyle interventions.
- SIGN Guideline No. 40 'Lipids and the prevention of Coronary Heart Disease' makes limited reference to the use of fish oils due to lack of assessment in primary prevention outcome studies.
- Further local advice on the place of Omacor in the treatment of post MI patients is being prepared by the Cardiovascular Formulary Sub-group. Prescribers are advised to await the issue of this advice before making a decision to initiate therapy.

Escitalopram (Cipralex^{Ò}) – depression **No.17/02**

- Escitalopram is the active isomer of the Selective Serotonin Re-uptake Inhibitor (SSRI) citalopram. It is licensed for the treatment of major depressive episodes and panic disorders.

Not recommended for use.
While escitalopram has been shown to be as effective as citalopram in short-term use, longer-term data are limited and do not address issues such as relapse, remission and withdrawal/rebound phenomena. No clear benefits are demonstrated over the parent product- citalopram.
However, the licence holder has indicated their decision to resubmit in light of additional information now being available.

Local points for consideration:

- Citalopram is now available in a generic form and a cost differential in favour of citalopram is anticipated.
- No SSRI has been shown to be more effective than another in the treatment of depression.
- Fluoxetine is currently the least expensive SSRI.
- Citalopram is not stocked by the hospital pharmacy.

Fondaparinux (Arixtra®) – prevention of venous thromboembolic events **No.18/02**

- Fondaparinux is a synthetic antithrombotic that inhibits Factor Xa without affecting thrombin itself. It is licensed for prevention of venous thromboembolic (VT) events in patients undergoing major orthopaedic surgery of the lower limbs.

Appropriate for use.
Compared with enoxaparin, fondaparinux has been shown to be associated with fewer thrombo-embolic events and a generally similar incidence of major bleeding. It is licensed for post-operative initiation, and this represents an advantage where regional anaesthesia and/or catheterisation are planned. It is predicted to be a cost effective alternative to enoxaparin in a robust economic model. It may be considered for patients for whom antithrombotic therapy is appropriate, recognising that other antithrombotic agents and other approaches to prophylaxis may be more suitable in some situations.

Consideration should be given to the following:

- Fondaparinux is restricted to secondary care.
- Fondaparinux has not been compared to heparins other than enoxaparin or to other approaches to prophylaxis of post-operative thromboembolism.
- Dalteparin (Fragmin®) is the antithrombotic used locally for VT prophylaxis.
- Refer to SIGN Guideline No.62 'Prophylaxis of venous thromboembolism' for further advice on VT prophylaxis during orthopaedic surgery.

SMC Work Programme

A list of forthcoming assessments, with expected date of issue of final advice, is available on the SMC website (www.scottishmedicines.org.uk) under 'Work Programme'.

Contact details
Local implementation of SMC recommendations is being taken forward by the Tayside Medicines Unit – contact Jan Jones, Pharmaceutical Prescribing Adviser (jan.jones@tpct.scot.nhs.uk) if you have any queries in relation to the introduction of new drugs within NHS Tayside

Comments on other matters to be raised with the Tayside Drug & Therapeutics Committee should be sent to Doreen Wilkie, Pharmacy Department, Ninewells Hospital. **doreen.wilkie@tuht.scot.nhs.uk**