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Drugs currently being considered by the SMC with advice due on 8 March 2004:

- Rosiglitazone and metformin combination (Avandamet®)
- Cilostazol (Pletal®)
- Alteplase (Actilyse®)
- Clopidogrel (Plavix®) plus aspirin
- Anastrozole (Arimidex®)
- Rosiglitazone (Avandia®)

A strengthened role for the Scottish Medicines Consortium (SMC) –
NHS HDL (2003) 60

The above circular explains the enhanced role of the SMC and the arrangements for a new process to ensure the national implementation of innovative new drugs. The remit of the SMC will continue to be –

“To provide advice to NHS Boards and their Area Drug and Therapeutics Committees (ADTCs) across Scotland about the status of all newly licensed medicines, all formulations of existing medicines and any major new indications for established products. This advice will be available as soon as practical after the launch of the product involved”
Drugs to be reviewed by the SMC will be placed into one of the following categories:

- Unique drugs for specific conditions which, if approved by SMC, will be introduced into NHSScotland following an agreed national programme.
- Drugs for conditions where alternative drug treatments already exist, which if approved by SMC, the implementation will be subject to individual NHS Board recommendations. (In practice, use of drugs in this category will be subject to Lanarkshire Area Drug and Therapeutics Committee approval for inclusion in the NHS Lanarkshire Joint Formulary.

In addition SMC will ‘horizon scan’ to provide early warning of truly new innovative drug treatments likely to have a major impact on clinical practice.

**Unique** drugs recommended by SMC must be made available uniformly across Scotland according to a national implementation plan. These drugs should be provided to meet clinical need within 3 months of publication of the SMC advice. Boards must follow the national plan.

NHS Boards must fund the cost of SMC recommendations from their general revenue allocations.

**BAN to rINN – Change of drug names**

From December 2003, in the UK, all drugs should be prescribed using the Recommended International Non-proprietary Name (rINN) instead of the British Approved Name. Most drugs are already prescribed by their rINN, however some changes will be necessary and the list is extensive.

- e.g. thyroxine will become levothyroxine
  - bendrofluazide will become bendroflumethiazide
  - frusemide will become furosemide

Up until now BANs have been used in the UK with dual labelling of rINNs. This change will bring the UK in line with the rest of Europe and should reduce the potential for medication errors. Electronic prescribing systems will change over gradually.

- Check the BNF No 46 page x for name changes
- Explain changes to patients
- Handwritten prescriptions should now show the new names
- The only exceptions are noradrenaline and adrenaline, which will not change to the new names (norepinephrine and epinephrine respectively).

**REMINDER – PRESCRIBING OF SELECTIVE SEROTONIN REUPTAKE INHIBITORS FOR CHILDREN AND ADOLESCENTS WITH MAJOR DEPRESSIVE DISORDERS**

- Paroxetine, venlafaxine, sertraline, citalopram and escitalopram are contra-indicated in paediatric major depressive disorder in the under 18s
There are no data on the safety and efficacy of fluvoxamine in paediatric depressive illness. This drug should not be used in the under 18s.

The balance of risks and benefits of fluoxetine in the treatment of major depressive disorder in under 18s appears to be favourable.

Fluoxetine does not have a marketing authorisation for major depressive disorder in under 18s. A decision to prescribe for a patient in this age group should be made with specialist advice.

Antidepressants should not be stopped abruptly. A gradual decrease in dose is advised.

A COMMON UNDERSTANDING – GUIDANCE ON JOINT WORKING BETWEEN NHSSCOTLAND AND THE PHARMACEUTICAL INDUSTRY (Scottish Executive 2003)

The Right Medicine: A Strategy for Pharmaceutical Care in Scotland was published in February 2002. A major action point was to produce guidance on joint working between NHSScotland and the pharmaceutical industry to ensure common understanding and improve patient care. The guidance aims to establish a common understanding on joint working by highlighting examples of good practice. Some of the important points to note from the guidance are:

- All joint working must be for the benefit of patients.
- All patient identification should be removed from data as per the Data Protection Act to preserve patient confidentiality.
- Development of protocols and/or guidelines should be under the control of the NHS.
- All joint working projects must promote and enhance equitable access to evidence-based healthcare.
- Joint working should not undermine or conflict with the ethical requirements of any healthcare professional.
- The interests of individual patients must be protected.
- The joint working agreement should not be seen as an endorsement or promotion of a specific medicine or technology.
- Reports or information about joint projects should not be used or published without the permission of all partners entering the agreement.
- The Pharmaceutical Industry must comply with the relevant Code of Practice at all times.
- All NHSScotland employees/independent contractors involved must comply with NHS (and relevant professional bodies) codes of conduct.
- Clinicians requesting addition of a medicine to the Lanarkshire Joint Formulary must provide a ‘declaration of interest’ e.g. company shares or industry research grants and ensure that decisions are based on clinical and cost-effectiveness information.

The following new drugs have been reviewed by the Scottish Medicines Consortium in December, January and February: -
<table>
<thead>
<tr>
<th>Date of SMC recommendation</th>
<th>Drug/product</th>
<th>Indication</th>
<th>SMC recommendation</th>
<th>Lanarkshire recommendation and ADTC comments</th>
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<tbody>
<tr>
<td>08/12/03 No 71/03</td>
<td>Teriparatide (Forsteo®)</td>
<td>Treatment of established (severe) osteoporosis in postmenopausal women. Osteoporosis is categorised as severe or established in the presence of one or more fragility fractures</td>
<td>Teriparatide is accepted for restricted use within NHS Scotland for the treatment of established (severe) osteoporosis in post-menopausal women. This medicine should be restricted to initiation by specialists experienced in the treatment of osteoporosis following assessment of fracture risk including measurement of bone mineral density (BMD)</td>
<td>The ADTC endorsed the recommendation of the SMC with the proviso that this drug is referred to the Rheumatology sub-group for discussion and local recommendations</td>
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<tr>
<td>08/12/03 No 81/03</td>
<td>Adalimumab (Humira®)</td>
<td>Treatment of moderate to severe, active rheumatoid arthritis in adult patients when the response to disease modifying anti-rheumatic drugs including methotrexate has been inadequate.</td>
<td>Adalimumab is accepted for restricted use in NHS Scotland for the treatment of rheumatoid arthritis (RA). It should be initiated only by a specialist experienced in the diagnosis and treatment of RA, and used in accordance with British Society Rheumatology (BSR) guidelines for prescribing TNF-α blockers in adults</td>
<td>The ADTC endorsed the recommendation of the SMC. Noted that alternative similar drugs were already in use. Rheumatology sub-group to provide local recommendations</td>
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<td>08/12/03 No 82/03</td>
<td>Fluticasone/ Salmeterol (Seretide Accuhaler®)</td>
<td>The symptomatic treatment of patients with severe chronic obstructive pulmonary disease (COPD), with FEV1 &lt;50% predicted normal, and a history of repeated exacerbations, who have significant symptoms despite regular bronchodilator therapy.</td>
<td>Fluticasone/salmeterol is accepted for use within NHS Scotland for the treatment of patients with severe chronic obstructive pulmonary disease. The combination appears to improve lung function to a greater extent than either of the individual drugs given alone. The combination product offers ease of administration and additional convenience</td>
<td>The ADTC endorsed the SMC recommendation. To be referred to the Respiratory sub-group for further comment.</td>
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<td>08/12/03</td>
<td>Testosterone gel (Testogel®)</td>
<td>Testosterone replacement therapy for male hypogonadism when testosterone deficiency has been confirmed by clinical features and biochemical tests. It is not licensed for use in patients aged &lt;18 years.</td>
<td><strong>Testosterone gel</strong> is accepted for restricted use within NHS Scotland. It offers an alternative to testosterone patches for those patients requiring a transdermal delivery system. The gel is at least as effective as patches and costs less. The gel is however significantly more expensive than other routes of administering this medicine.</td>
<td>The ADTC endorsed the recommendation of the SMC. This formulation will be referred to the Diabetes sub-group to determine place in therapy.</td>
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<td>12/01/04</td>
<td>Zoledronic acid (Zometa®)</td>
<td>The prevention of skeletal related events in patients with advanced prostate cancer involving bone.</td>
<td><strong>Zoledronic acid</strong> is not recommended for use within NHS Scotland for the prevention of skeletal related events (SREs) in patients with advanced prostate cancer involving bone.</td>
<td>The ADTC endorsed the recommendation of the SMC and zoledronic acid should not be prescribed in Lanarkshire, for this indication.</td>
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<td>12/01/04</td>
<td>Propofol 1% emulsion (Propofol Lipuro®)</td>
<td>Induction and maintenance of general anaesthesia, sedation of ventilated patients in intensive care and sedation for diagnostic and surgical procedures, alone or in combination with local or regional anaesthesia.</td>
<td><strong>Accepted for use in NHS Scotland.</strong> Propofol MCT-LCT emulsion 1% is a new formulation of an existing product. It is as effective as alternative formulations of propofol. Pain on injection is significantly reduced in frequency and intensity compared with alternative formulations, though not totally eliminated. The major advantage is realised if co-administration of lignocaine is unnecessary.</td>
<td>The ADTC endorsed the recommendation of the SMC but deferred a final decision on use in Lanarkshire pending details of acquisition costs compared to the other formulations already available.</td>
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<td>12/01/04</td>
<td>Memantine (Ebixa®)</td>
<td>Treatment of patients with moderately severe to severe Alzheimer’s disease (AD)</td>
<td>Following a resubmission to SMC memantine is not recommended for use within NHS Scotland.</td>
<td>The ADTC endorsed the SMC recommendation and memantine should not be prescribed for new patients in Lanarkshire.</td>
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<td>12/01/04</td>
<td>Caspofungin (Cancidas®)</td>
<td>Invasive candidiasis in non-neutropenic adults.</td>
<td><strong>Accepted for restricted use in NHS Scotland.</strong> Its use should be restricted to patients with fluconazole resistant <em>Candida</em> infection who do not respond to, or cannot tolerate amphotericin B therapy or who are at increased risk of serious side effects with amphotericin (e.g. transplant patients, especially those receiving bone marrow transplants)</td>
<td>The ADTC endorsed the SMC recommendation. This drug to be referred to microbiologists, haematologists and oncologists for comment.</td>
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<td>12/01/04 No 75/03</td>
<td>Topiramate (Topamax®)</td>
<td>Monotherapy of epilepsy in adults and children aged 6 years and above. Add on therapy for adults and children &gt; 2 years.</td>
<td>Topiramate is accepted for restricted use in NHS Scotland for its extended (monotherapy) indication. It should be initiated only by physicians with experience in the treatment of epilepsy. Its use for second line therapy is unaffected by this recommendation.</td>
<td>The ADTC endorsed the SMC recommendation with a request for comment from the neurology specialists.</td>
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<td>12/01/04 No 84/03</td>
<td>Pegylated liposomal doxorubicin (Caelyx®)</td>
<td>Metastatic breast cancer as monotherapy, where there is an increased risk of cardiotoxicity</td>
<td>Not recommended for use in NHS Scotland. Less cardiotoxic than conventional doxorubicin, but associated with other troublesome adverse effects, particularly palmar – plantar erythrodysesthesia. Significantly more expensive than the standard doxorubicin formulation</td>
<td>The ADTC endorsed the SMC recommendation and this formulation of doxorubicin should not be prescribed in Lanarkshire.</td>
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<td>12/01/04 No 85/03</td>
<td>Levodopa, carbidopa and entacapone (Stalevo®)</td>
<td>Treatment of patients with Parkinson’s disease and end of dose motor fluctuations not stabilised on levodopa/dopa decarboxylase inhibitor treatment</td>
<td>Accepted for use in NHS Scotland. This combination allows administration of a single tablet incorporating ingredients routinely combined for the listed indication. This may improve convenience to the patient. Depending on the doses and formulations being replaced, conversion to the combination may result in a modest increase in cost or (less commonly) a cost saving.</td>
<td>The ADTC endorsed the recommendation of the SMC.</td>
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<td>09/02/04 No 49/03</td>
<td>Frovatriptan (Migard®)</td>
<td>Acute treatment of the headache phase of migraine with or without aura</td>
<td>Frovatriptan is accepted for use within NHS Scotland for the treatment of the headache phase of migraine attacks with or without aura. It is the seventh 5HT1 agonist to be marketed. It is less expensive than existing drugs</td>
<td>ADTC endorsed the SMC recommendation. To be referred to the neurologists to agree formulary status.</td>
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<tr>
<td>09/02/04 No 60/04</td>
<td>Travoprost (Travatan®)</td>
<td>First line treatment of ocular hypertension or open-angle glaucoma</td>
<td>Travoprost is accepted for restricted use in NHS Scotland for the treatment of raised intraocular pressure (IOP) in patients who have contra-indications to beta blockers or have a history of adverse reactions to this group of drugs. It may also be indicated in addition to beta blockers when required</td>
<td>ADTC endorsed the SMC recommendation. To be referred to the ophthalmology sub-group to agree formulary status.</td>
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<tr>
<td>09/02/04 No 76/04</td>
<td>Fluvastatin XL (Lescol XL®)</td>
<td>Secondary prevention of coronary events following percutaneous coronary intervention (PCI)</td>
<td>Fluvastatin is accepted for restricted use in NHS Scotland for the secondary prevention of coronary events after percutaneous coronary angioplasty (PCI). Fluvastatin is best placed for the management of patients previously untreated with a statin.</td>
<td>ADTC endorsed the SMC recommendation. Cardiology sub-group to agree formulary status.</td>
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