TAYSIDE PRESCRIBER

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MECHANISM FOR INTRODUCING NEW DRUGS IN PRACTICE

This topic formed the main business at the most recent ADTC meeting.

To recap, it is now necessary to **refer new drugs for review by the Drug Evaluation Panel** (DEP) *before* their introduction in TUHT and *before* advice can be given to prescribers in Primary Care.

- A **Submission Form** (available from the Medicines Information Centre in Dept of Pharmacy at Ninewells Hospital, Telephone: 01382 660111 Ext: 32351) must first be completed. Individuals can submit directly to the DEP but, in TUHT, only with the knowledge of their Clinical Group Director who must also sign the Submission Form.
- The following information is required:
  - A detailed product profile.
  - A statement of the supporting evidence of efficacy.
  - A pharmaco-economic evaluation.
  - An estimate of the anticipated health gain.
  - A protocol for use of the drug.

It is hoped to process applications timeously and reach a decision within 2-3 months.

Prioritisation and funding issues will in future be addressed by an executive consisting of representatives of the Trust management bodies and Tayside Health Board acting on information and advice on cost-effectiveness provided by ADTC. A proposal to this effect is being put to the Trusts and Health Board.

As part of the advice given, each new drug is assigned a prescribing category. These are:

Category 1. Recommendation for general use
Category 2. On recommendation of specialist
2 (a) hospital use only
2 (b) shared care
Category 3. Not recommended - does not offer advantages over existing therapy
Category 4. Effectiveness or place in treatment not yet established

The above are recommendations only - GPs are nevertheless free to prescribe licensed medicines for individuals if they wish to do so. It is hoped, however, that account will be taken of the evidence (or lack of it) on which a recommendation is based.

SHARED CARE

This is often a particularly thorny issue. The decision to "share" care or responsibility for a treatment between the GP and specialist is one that must be agreed by both parties. A clear statement (treatment protocol) as to how the treatment will be "shared" in practice is required and there should be some indication of the way in which the cost of treatment is to be met. The issue of shared care is to be reviewed by the TPCT Drug & Therapeutics Committee who will produce guidelines for GPs and specialists in the future.

NEW DRUG EVALUATIONS

Drug: Bupropion (Zyban®)
Indication: Smoking cessation
Category: 4 - Effectiveness or place in treatment not yet established
Main consideration(s) The place of bupropion in treatment is so far very limited. It has only been investigated as an adjunct to intensive support/counselling in highly motivated people wishing to stop smoking and this should reflect its use in practice until further evidence is forthcoming.
Comments ▪ In two randomised controlled trials, the number of people treated with bupropion in conjunction with intensive/support counselling still not smoking after 1 year was 18% compared with 9% who received intensive counselling/support alone. ▪ There are no published longer term outcome data. ▪ Bupropion has not been shown to be effective without intensive counselling/support in highly motivated subjects. ▪ Smoking is undoubtedly an effective secondary prevention measure for diabetics and those with established cardiovascular, peripheral vascular/cerebrovascular or respiratory disease. There is however no reported experience of bupropion in such high risk groups who were excluded from the published clinical trials - although the Product Licence for Zyban® does not preclude the use of bupropion if otherwise indicated. ▪ Bupropion has potential side effects (e.g. GI upsets, anxiety, agitation, sleep disturbances and a risk of seizures), interacts with anti-epileptic drugs, antidepressants and other CNS drugs, and is contraindicated in those with a history of seizures, bipolar (mood) disorders, and in conjunction with monoamine oxidase inhibitors. ▪ Bupropion is unlicensed for the under 18s or pregnant subjects (priority targets for smoking cessation measures) and must be used with caution in the elderly and those with liver impairment.

Drug:	Rosiglitazone (Avandia®)
Indication:	Type 2 diabetes mellitus
Category:	1 – Recommendation for general use

Main consideration(s)

Rosiglitazone is the first of a series of drugs of its class. It is indicated *only as an add-on therapy* in combination with:

- Metformin - when there is poor control on metformin monotherapy
- A sulphonylurea - for patients who are intolerant of metformin or for whom metformin is otherwise contraindicated.

Comments

- Rosiglitazone is not licensed for monotherapy or for use in combination with insulin.
- Neither is it licensed for use in combination with metformin + sulphonylurea (triple therapy) and it would be impractical to discontinue one of these in order to add in rosiglitazone since in takes around 6-8 weeks to exert its full effect.
- Rosiglitazone produces a modest ↓ in HbA_{1c} of around 1-2%.
- Only modest ↓ in cholesterol (but does ↑ HDL and ↓ LDL/HDL ratio: triglycerides may also fall if initially very high).
- Monitor LFTs every 2 months for 1st year then "periodically" thereafter.
- Weight gain (average 2 kg) and fluid retention are relatively common.
- Rosiglitazone is contraindicated in patients with a history of congestive heart failure.

Drug:	Leflunomide (Arava®)
Indication:	Active rheumatoid arthritis in adults
Category:	2(b) – On recommendation of specialist: shared care

Main consideration(s)

- Leflunomide is a new disease modifying anti-rheumatic drug (DMARD). In randomised controlled trials it has been shown to be as effective as sulphasalazine or methotrexate.
- Treatment should be reserved for patients not controlled on first-line DMARDs (e.g. sulphasalazine, methotrexate) or unable to tolerate these drugs.

Comments

- Assessment of patients for leflunomide therapy should be undertaken by a rheumatologist.
- Treatment should be agreed with the GP along with a suitable protocol which sets out the responsibility of both specialist and GP in line with the monitoring of other DMARD therapies.

Your views on any aspect of the introduction of new drugs in practice are welcomed. Comments should be sent to: Mr Peter Clough, Secretary to ADTC, Department of Pharmacy, Ninewells Hospital. Telephone: 01382 660111 Ext: 32351. e-mail druginfo@tuht.scot.nhs.uk