DEVELOPMENT OF LOCAL NEW MEDICINE TREATMENT PROTOCOLS

GUIDANCE NOTES

The following guidance has been developed by the Medicines Advisory Group (MAG) to assist specialist teams in drawing up Local New Medicine Treatment Protocols to define patient selection criteria, prescriber details and monitoring requirements in relation to the prescribing of new medicines.

Local Treatment Protocols are required by MAG for new medicines that are categorised as appropriate for use within Specialist Treatment Pathways* **and** where the introduction of the new medicine is associated with high clinical or financial risk.

The points below relate directly to the areas to be completed in the "New Medicine Treatment Protocol Template" (available in word and able to be downloaded from the DTC website - posted under New Medicines, MAG Processes, New Medicine Treatment Protocols). Completed protocols should be submitted to Dr Jan Jones, Tayside Medicines Unit.

* place in therapy of new medicine is beyond first and second-line formulary choices (refer to "MAG Categorisation of SMC Recommendations" available on the DTC website).

2. Licensed indication(s): give the indication(s) for which the medicine will be used in this instance.

3. National recommendations: give the relevant advice that has been issued by SMC.

4. Prescriber details: state if this is a hospital only treatment. Provide details of supply where appropriate, for example:
re topical tacrolimus:

'*Prescription will be from hospital pharmacy via pre-prepared NHS Tayside forms'*

re teriparatide:

'*Treatment is distributed by the FORSTEO Homecare Programme – all registration forms to be sent to Ninewells Pharmacy fao Gordon Thomson'*

List the grades of staff who will prescribing the medicine eg registrars and consultants or doctors in a particular area/clinic eg: 'doctors in the bone clinic', 'respiratory physicians', 'paediatricians',

5. Patient criteria: describe which patients should be offered this new medicine giving a brief description of what, if any, treatment should have been tried before embarking on treatment with the new medicine, for example:
re topical tacrolimus:

'Conventional treatment with topical emollient / steroid regimens will remain for now the mainstay of treatment for most patients with atopic dermatitis (eczema). Use of topical tacrolimus may however be considered as an alternative to systemic therapy (as is the case with phototherapy) in the following situations:

Body eczema – when requiring continuous use of potent topical steroid
Facial eczema – when requiring continuous use of moderate strength topical steroid
Skin atrophy – tacrolimus appears not to be associated with impaired collagen synthesis or thinning of the skin'.

re teriparatide:

'Treatment should be considered only in postmenopausal women with WHO defined osteoporosis, i.e. T-score less than –2.5, and who ALSO fulfil the following criteria:

i) at least 2 vertebral fragility fractures with a Z-score of less than –2.0 (i.e. "severe osteoporosis")
OR
ii) fragility fractures despite having been on a bisphosphonate for at least 12 months.'

If the new medicine is to be used in patients unresponsive or intolerant of alternative treatments, define the terms “unresponsive” and “intolerant”.
If a wider disease management protocol already exists, please attach a copy and indicate where this new medicine would be incorporated.

6. Administration details: provide information on recommended dosage and, if appropriate, duration of treatment

7. Contra-indications: list any contra-indications to treatment

8. Side-effects and cautions: list the main side-effects of this drug and any cautions that it is important to be aware of.

9. Monitoring – response to treatment: describe procedures to be put in place for monitoring patient response to treatment, including:

- how often the patient should be reviewed and by whom
- how response will be monitored eg blood tests, respiratory function tests, pain scores etc..
- after what duration treatment should be discontinued if there is no response

A register should be kept for the new drug with patient CHI number, drug name and indication.

10. Monitoring – treatment safety: describe procedures to be put in place for monitoring safety. Include details of planned audits if appropriate.

11. Written by: treatment protocols should be written by a relevant consultant in liaison with their clinical principal pharmacist, and approved by the relevant Clinical Team Leader (ASD), Lead Clinician (PSD).

12. Review date: a review date of one year is normal. Review is the responsibility of the original author.