POST-STUDY MANAGEMENT OF PATIENTS IN DRUG TRIALS

In the case of clinical trials of medicinal products (drug trials), Tayside R&D have agreed to bring to the attention of researchers and research sponsors the following statement by NHS Tayside Drug & Therapeutics Committee on behalf of NHS Tayside.

The NHS Tayside Drug & Therapeutics Committee does not recommend the prescribing of new medicines until they have been evaluated and approved by the Scottish Medicines Consortium (SMC). Therefore, where patients are treated with new medicines in clinical trials, the following post-study options should apply.

Post-study management options

- Treatment with an *unlicensed medicine* should only be continued for an individual patient where it is provided free of charge by the manufacturer/supplier.

- A licensed medicine that *has been approved* for use by the SMC can continue to be prescribed where indicated*.

- A licensed medicine *not yet submitted* for evaluation by the SMC should not be prescribed at the end of a study. See appeal mechanism below**.

- A licensed medicine that has been submitted but *not yet evaluated* by the SMC may continue to be prescribed subject to review once SMC advice is available*.

- A licensed medicine *not approved* for use by the SMC should not be prescribed at the end of a study. See appeal mechanism below**.

- *Cancer chemotherapy agents* may continue to be prescribed where supplied free of charge for use within a named-patient programme by arrangement with the manufacturer or supplier.

* The GP will make decisions about the continued use of a trial drug where it is to be prescribed in Primary Care. The researcher should provide sufficient information on the outcome of the study to inform such a decision. The GP should be advised of the continued use of specialist drugs prescribed in secondary care and be party to any decision to continue trial drugs as part of a shared care agreement.

** An appeal mechanism exists to allow the consideration of exceptional treatment of individual patients funded from existing budgets within Clinical Groups and with the knowledge and approval of the Clinical Group Director (further advice from DTC). There is also an appeal mechanism in the Mental Health Directorate and each of the LHCCs (Community Health Partnerships from April 2005).

Tayside Drug & Therapeutics Committee, November 2004

For further details see *"Post-Study Management of Patients in Drug Trials"*, available on request from the Medical Advisor, R&D/Ethics Office, Level 9, Ninewells Hospital & Medical School, Dundee, DD1 9SY (Telephone 01382 632589 or Ninewells extension 32589).