

Distribution: Public Hospitals

Subject: Highly Specialised Drugs Program - Guidelines For Undertaking Clinical Trials

Purpose

The purpose of this circular is to advise public hospitals of guidelines recommended by the Highly Specialised Drugs Working Party in determining economical appropriateness of clinical trials on their premises.

The Highly Specialised Drugs Working Party (HSDWP) is a committee of Commonwealth, State and Territory Officials established under the Australian Health Ministers' Advisory Council to advise on funding aspects of certain highly specialised drugs.

The HSDWP has recently been discussing ways to assist in ensuring the cost effectiveness of major new drugs supplied through public hospitals. The HSDWP appreciates that as often clinical trials are carried out in public teaching hospitals there are short term cost implications of such trials for the hospitals and, in the longer term, can influence the use and cost of the drugs after marketing approval.

It is generally recognised that the PBS system provides a reasonable mechanism for negotiating reasonable costs for PBS listed drugs. There is however, no such mechanism for public hospitals involved in clinical trials to influence the eventual purchase price of innovative drugs that are prescribed by clinicians but are not listed on the PBS.

Accordingly, AHMAC has requested that the HSDWP advise State/Territory Health Departments of Working Party recommendations aimed at allowing the purchaser control over the conditions of supply. The HSDWP has developed guidelines covering economic matters for use by public hospitals in considering whether it is appropriate for a clinical trial to be conducted on its premises. Such considerations should commence at the earliest possible stage when sponsors approach specialists to make applications to the hospitals institutional ethics committees to conduct drug trials. The guidelines recommended by the HSDWP are:

- a) Sponsors of products intended for clinical trials should be required to provide a firm indication of the product price following eventual marketing approval. At the present time, many sponsors refuse to specify, at the trial stage, the subsequent purchase price or price range for the drug at the trial stage. Sponsors should provide hospitals with information on the potential financial implications of maintaining patients on their products if the clinical trial demonstrates acceptable safety and efficacy and marketing approval is gained.

- b) Sponsors should be expected, when appropriate, to design clinical trials to include gathering of data on the value for money of the drug for the use under investigation.
- c) Sponsors should undertake to meet all the reasonable direct and indirect costs to hospitals in conducting clinical trials. Over recent years there has been a tendency for sponsors not to meet all the legitimate costs of conducting drug trials. On occasions, only the drug has been provided by the company without any other financial assistance for the trial.
- d) Sponsors should undertake not to introduce any "administration fees" in the period following a drug trial and leading up to registration for marketing, or be prepared to justify any fee.

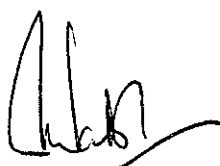
Some manufacturers do not, or are slow, in seeking marketing approval and have introduced "administration fees" for the supply of drugs under the Special Access Scheme (SAS) following the conclusion of clinical trials. These are solely determined by the manufacturer and in many cases are equivalent to the intended product price after marketing approval.

It should be noted that the Therapeutic Goods Administration is considering placing a limit on the volume of a product's use under the Special Access Scheme to prevent the Scheme being used as an alternative to marketing.

- e) Sponsors should undertake to pay hospitals for preparing individual case reports for products provided through the Special Access Scheme. Some suppliers require ongoing patient profiles during treatment.
- f) Unregistered products used in clinical trials cannot be promoted by the sponsor. Hospital staff should be made aware of the code of conduct of the Australian Pharmaceutical Sponsors Association. By this code, the Industry self-regulates promotion of pharmaceutical products. Any infringement of the code should be reported to:

Secretary
Code of Conduct Subcommittee
Australian Pharmaceutical Manufacturers Association
Level 2, 77 Berry Street
NORTH SYDNEY NSW 2060

I would appreciate your co-operation in circulating these guidelines to all relevant staff.



DR MICHAEL WALSH
DIRECTOR
ACUTE HEALTH SERVICES