Drugs - Highly Specialised Program - Guidelines for Undertaking Clinical Trials

Summary
Requirement in determining economical appropriateness of clinical trials of highly specialised drugs on hospital premises.

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Author branch
Office for Health and Medical Research

Branch contact
9879 3214

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Area Health Services/Chief Executive Governed Statutory Health Corporation, Board Governed Statutory Health Corporations, Affiliated Health Organisations, Divisions of General Practice, Ministry of Health, Private Hospitals and day Procedure Centres, Public Health Units, Public Hospitals

Distributed to
Public Health System, Divisions of General Practice, Ministry of Health, Public Health Units, Public Hospitals, Private Hospitals and Day Procedure Centres

Audience

Secretary, NSW Health
This Policy Directive may be varied, withdrawn or replaced at any time. Compliance with this directive is mandatory for NSW Health and is a condition of subsidy for public health organisations.
**Highly Specialised Drugs Program - Guidelines for Undertaking Clinical Trials**

The purpose of this circular is to advise 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 (AHMAC) 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 clinical trials often carried out in public teaching hospitals have short term cost implications for the hospitals and, in the longer term, can influence the use and cost of the drugs after marketing approval.

The PBS system provides a 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.

In view of this, 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:

1. Sponsors of products intended for clinical trials should be required to provide a firm indication of the product price following eventual marketing approval. Presently, many sponsors refuse to specify, at the trial stage, the subsequent purchase price or price range for the drug. 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 obtained.

2. 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.

3. 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. At times, companies provide only the drug without any other financial assistance for the trial.

4. 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.

5. 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.

6. 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 Manufactures Association
   Level 2, 77 Berry Street
   NORTH SYDNEY NSW 2060

Please circulate these guidelines to all relevant staff.

JOHN WYN OWEN
Director-General