

Doctors' Relationships with the Pharmaceutical Industry

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1. Preamble

The Australian Medical Association considers that its Code of Ethics, which is amended periodically so as to remain a relevant, contemporary statement of ethical principles, provides adequate advice on ethical behaviour for practising doctors in most circumstances. On occasions, however, elaboration of basic ethical principles will be appropriate, seeking to guide members as to the application of those principles in particular circumstances. Such is the purpose of these Guidelines.

2. Introduction

2.1 The history of health care delivery in Australia has been marked by close collaboration between doctors and the pharmaceutical and health supply industries. This collaboration has extended to research as well as education. There is no doubt that it has been of benefit to the health care that Australians have been able to receive.

2.2 However, since medicine is a self-governing profession, doctors have a responsibility to ensure that their participation in such collaborative efforts is consistent with their duties towards their patients and towards society at large.

2.3 The following are put forward by the Australian Medical Association to guide members in their interactions with the pharmaceutical industry in this light. Although, in these guidelines, the specific focus is the relationship between doctors and the pharmaceutical industry, the Association believes that, with due alteration of detail, the same considerations apply to the relationship between doctors and manufacturers of medical devices, infant formulae and similar products, and health care product and service suppliers in general.

2.4 Transparency of arrangements between doctors and the pharmaceutical industry, by disclosure of financial or other arrangements to peers, patients and Ethics Committees, will improve confidence in the self-government role of the medical profession

3. The Guidelines in relation to Medical Students, Interns and Residents

3.1 The Australian Medical Association believes that anyone who enters the profession of medicine thereby accepts the responsibility to be guided principally by considerations of patient welfare. The Association further believes that with due alteration of detail, these considerations also apply to doctors-in-training. The Association therefore recommends that medical schools should establish policies which require formal teaching in this regard, so as to inculcate an appropriate ethical outlook in medical students.

3.2 Medical curricula should include formal training based on the Australian Medical Association Guidelines for an ethical association with the pharmaceutical industry.

4. The Relationship between the Pharmaceutical Industry, Doctors & Patients

4.1 Professional interactions between doctors and the pharmaceutical industry should have as their primary objective the advancement of the health of patients rather than the self interests of either doctors or members of the industry.

4.2 The relationship of doctors with the pharmaceutical industry is subject to the general constraints of the code of ethics of the medical profession.

- 4.3 The doctor/patient relationship is based on trust, and involves the obligation to safeguard the welfare and the confidentiality of the patient, and to advance the patient's access to appropriate health care.
- 4.4 The practising doctor's primary obligation is towards the patient. Considerations involving the pharmaceutical industry are appropriate only insofar as they do not intrude into or distort that primary obligation.
- 4.5 In any association between a doctor not employed by the pharmaceutical industry and the industry itself, the doctor should always maintain professional autonomy, independence and commitment to the scientific method.

5. Research

- 5.1 Medical Research requires active cooperation between the medical profession and the pharmaceutical industry.
- 5.2 Before participating in any research project, doctors should satisfy themselves that the project has genuine merit, is not detrimental to the development of other more appropriate areas of research and is ethically defensible, socially responsible and scientifically valid.
- 5.3 The participation of doctors in research activities sponsored by the pharmaceutical industry should always be preceded by formal approval of the project by an appropriate review body, which should also receive a report of the project upon its completion. Such review should follow national guidelines of the type promulgated by the National Health and Medical Research Council, the Australian Health Ethics Committee, and similar bodies.
- 5.4 All monies provided for research, should be held in trust for the specified purposes. Such an account should be available for audit.
- 5.5 Budget for the research projects, including source distribution, should be subject to scrutiny by an Ethics Committee.

6 Post-marketing Surveillance Studies

- 6.1 The development of therapeutic pharmaceuticals is a complicated process that involves many steps. Since sooner or later pharmaceuticals have to be freed for non-investigational use, it is appropriate for doctors in clinical practice to participate in appropriately designed surveillance studies (post-marketing surveillance studies). The purpose of these is to monitor the performance of the medicament under conditions of actual use.
- 6.2 Doctors are encouraged to participate only in scientifically appropriate surveillance studies of drugs relevant to their area of practice. The degree and manner of their participation should be in keeping with generally accepted standards of ethical medical practice and research.
- 6.3 The Australian Medical Association is concerned that marketing programs not masquerade as surveillance studies. The Association therefore recommends that:
- 6.4 Doctors contemplating participation in surveillance studies should avail themselves of appropriate resources to assist them in their decision-making. Review boards and ethics committees which already exist may serve in this capacity. Reference to such an Ethics Committee may be required for PMS studies in certain circumstances - for example, if patients are to be approached for information beyond that which would normally be required, or additional investigations are to be performed, or if it is proposed to allocate patients systematically to treatments.

- 6.5 It is ethically acceptable for doctors to receive remuneration for participation in approved surveillance studies only when such participation involves a significant amount of professional time and skill over and above that applied directly to patient care. This remuneration should be appropriate to the professional time and skill required and not constitute an enticement to inappropriate prescribing. It may, however, involve reimbursement of opportunity costs. Parameters such as time expenditure, complexity of the study, etc. may also be relevant considerations.
- 6.6 Incremental costs - additional costs which are directly related to the surveillance study - whether these costs involve diagnostic procedures or patient services, should not be defrayed by Government or other insurance agencies but should be funded by the pharmaceutical manufacturer undertaking the study.
- 6.7 Patient participation in surveillance studies should occur only with the full, informed and competent consent of the patient. The prescribing/treating doctor has an obligation to ensure that the patient is fully aware:
- (a) that the doctor's continuing concern for the patient's welfare is not contingent on the patient's participation in the study;
 - (b) of available alternatives, their comparative advantages and/or disadvantages and other related matters that would establish informed consent under normal circumstances;
 - (c) that the patient may withdraw from the study at any time and return to the alternative therapies indicated insofar as that is medically feasible. Where it is anticipated that this may not be possible, the patient should be clearly informed of this at the outset; and
 - (c) Patients should be fully aware that the budget has been scrutinised by an Ethics Committee.
- 6.8 The Association believes that the National Health and Medical Research Committee's guidelines on research involving human subjects and guidelines on providing information to patients may serve as useful bases for structuring and obtaining the relevant consent.
- 6.9 The doctor who enrolls a patient in a surveillance study has an obligation to ensure the protection of the patient's identity if the patient so wishes. If the patient desires such protection but this cannot be guaranteed, the doctor should so inform the patient as part of the informed consent process for the study.
- 6.10 The results of any surveillance study should be made available for peer-review and/or publication in a refereed professional journal within a reasonable period.

7. Continuing Medical Education

- 7.1 Continuing medical education is essential but also expensive to develop and to provide. It is ethically acceptable for the pharmaceutical industry to contribute to such events provided these contributions are at arm's length and the following guidelines are met:
- 7.2 CME activities should address the educational needs of the targeted medical audience and not just the marketing needs of the contributing pharmaceutical company.
- 7.3 Doctor organisers should have the ultimate decision regarding the organisation, content and choice of CME activities.
- 7.4 CME organisers and their delegates must not be in a position of conflict of interest by virtue of any affiliation with the sponsor(s) of those activities.
- 7.5 The program for such activities may acknowledge the financial and/or other aid received, and may identify but not excessively promote the sponsor's product(s).

- 7.6 Travel and accommodation arrangements, social events, as well as venues for industry-sponsored CME activities should be in keeping with the arrangements which would normally obtain in the absence of industry sponsorship.

8. Clinical Evaluation Packages or Samples

- 8.1 Clinical evaluation packages or samples are packages containing pharmaceutical products distributed by pharmaceutical manufacturers or their agents to doctors. They allow prescribing doctors to evaluate an initial clinical response to a medication, permit them to initiate immediate therapy, and provide medications for those who cannot otherwise afford them. Although the latter use is laudable, the Australian Medical Association does not believe that such use comes to grips with the real problem of persons who are not currently caught by the Australian welfare net. The Australian Medical Association therefore maintains that the pharmaceutical industry and government should devise some means whereby patients who are indigent or socially disadvantaged but do not qualify for socially assisted access to pharmaceuticals and/or related products may be identified by their doctors and may receive the relevant products free of charge or at appropriate concessional rates. However, as a matter of general policy and in anticipation of appropriate moves in that direction, the AMA advises:
- 8.2 Distribution of samples should be solely for the purpose of allowing doctors to evaluate the clinical performance of the medications outside the context of post-marketing surveillance studies, to initiate therapy, or for similar purposes. Any departure from this use must be justifiable in terms of otherwise applicable principles of ethical medical practice.
- 8.3 Distribution of samples, etc. should not involve any form of material gain for the doctor or for the practice with which he or she is associated.
- 8.4 It is the accepting doctor's responsibility to ensure the age - related quality of the samples that he or she accepts as well as their security. The accepting doctor is also responsible for the proper disposal of any samples which are unused.

9. Infant Formulae and Similar Products

- 9.1 The Australian Medical Association believes that, because of their content, infant formulae and similar products should be treated as pharmaceuticals.
- 9.2 Infant formulae and similar products, as well as medical devices, etc., should be considered in the same light as pharmaceuticals. They should therefore be dealt with in a manner equivalent to that indicated by these guidelines for an ethical association between doctors and the pharmaceutical industry.

10. Dispensing Doctors and Related Issues

- 10.1 Practising doctors who also have a financial interest in dispensing pharmaceuticals or who offer their patients health-care related services or products outside the normal function of a doctor are in a prima facie position of conflict of interest. The Association therefore recommends that:
- 10.2 Doctors should not dispense pharmaceuticals, etc. for material gain unless there is no reasonable alternative. Furthermore, and for similar reasons.
- 10.3 Doctors should not knowingly invest in pharmaceutical manufacturing companies or related undertakings where knowledge about the success of the company or undertaking might be seen to influence inappropriately the manner of their practice or their prescribing behaviour.

- 10.4 Doctors in active practice should not be affiliated with pharmaceutical manufacturers if the nature of their affiliation influences their medical practice in an inappropriate fashion.

11. Industry Sponsored Meetings

- 11.1 The AMA acknowledges the right of the pharmaceutical industry to sponsor and engage speakers for meetings.
- 11.2 The Association rejects promotional and marketing activities under the guise of education.

12. Other Considerations

- 12.1 The primary way in which doctors inform themselves about new products, etc. should be through continuing medical education programs and a judicious study of the appropriate professional literature. However, representatives of pharmaceutical manufacturers seek out doctors in order to advertise pharmaceutical products. When such contact involves the transfer of considerations from the manufacturer or distributor to the doctor, the payment of a fee, emolument or some other such matter, there arises an appearance of impropriety.
- 12.2 Doctors in practice should not accept a fee or equivalent consideration from pharmaceutical manufacturers, distributors, etc. in exchange for seeing them in a promotional or similar capacity.
- 12.3 Practising doctors should not accept, nor allow their prescribing habits to be influenced by, personal gifts from the pharmaceutical industry or similar bodies.
- 12.4 Doctors in active practice may accept educational materials appropriate to their areas of practice.

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