



Victoria's Health Consumer Organisation

# THE ROYAL AUSTRALASIAN COLLEGE OF PHYSICIANS

## GUIDELINES FOR ETHICAL RELATIONSHIPS BETWEEN HEALTH PROFESSIONALS AND INDUSTRY

**Health Issues Centre Submission**

***31 October 2013***

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## Definitions

An ***interest*** is a commitment, goal, obligation or value associated with a social relationship or practice.

A ***duality*** is where two or more distinct interests co-exist in a decision making setting.

A ***conflict of interest*** exists when a particular relationship or practice gives rise to two or more conflicting interests.

### Reference

Guidelines for ethical relationships between physicians and industry, 4<sup>th</sup> edition 2013. Sydney, Australia.

## Executive Summary

Health Issues Centre applauds The Royal Australasian College of Physicians' commitment to patient safety and welfare and for involving consumers in the development and refinement of the fourth edition Guidelines for Ethical Relationships between Health Professionals and Industry.

Health Issues Centre aims to represent the voice of consumers in health issues across Victoria. The organisation promotes improvements to the healthcare system from the perspectives of consumers, with an emphasis on equity, as well as promoting and providing expertise on consumer participation in health and patient centred care.

It is through this health consumer-focused lens that we are responding to this consultation by The Royal Australasian College of Physicians (RACP). Our submission highlights the impact that poorly managed conflicts of interest between health professionals and industry can have on consumers. It also focuses on consumers' concerns about the potential for influence as a result of payments and transfers of value between industry and health professionals.

Our understanding of the purpose of these guidelines is to provide medical practitioners and professional societies with guidance and advice for assessing and managing the various relationships they have with industry. In so doing, the guidelines preserve public trust in the Australian healthcare system to provide ethical and quality care to patients. We, therefore, believe that in responding to the issues raised within these guidelines the perspective of consumers and their rights must be considered.

We have not attempted to answer all of the questions raised in the guidelines, but we have addressed those that we believe are most pertinent to consumers.

The most important of these are captured in the following themes:

- 1. Potential to influence:** From a consumer perspective, we believe that the most important question that health professionals must ask when identifying, assessing and managing conflicts of interest is the potential of the transfer of value to influence their behaviour and professional judgement in patient care. It is critical that health professionals preserve the trust placed in them to operate in the best interest of communities, free of any influence by industry.
- 2. Potential to involve consumers:** We acknowledge the challenge health-based organisations often face in dealing with conflicts of interest. By appointing skilled consumers onto existing governance or ethics committees, health services, institutes and professional societies benefit from:
  - working with consumers who understand and support the work they are looking to achieve
  - understanding community concerns in relation to dualities and actual conflicts of interest
  - an ability to act on these concerns in a timely and appropriate manner that upholds the trust communities place in health-based organisations to act in the best interest of consumers.

## Evidence (3.1.2)

Health Issues Centre strongly agrees with the proposed guidelines for medical practitioners to develop processes to critically evaluate any advertising and other forms of drug promotion materials distributed by pharmaceutical companies. The reality is that exposure to unsubstantiated materials can greatly affect the advice and prescribing behaviours of health professionals and, thus impact on the safety and wellbeing of consumers. Medical practitioners should in all cases seek advice from peers and contact organisations like Medicines Australia or Therapeutic Goods Administration when in doubt.

## Gifts (3.2.2)

The guidelines note the compelling evidence against medical practitioners accepting gifts from industry and the impact it can have on the independence of a clinician's judgement. Health Issues Centre supports the RACP's recommendation that health professionals not accept gifts of any value and believes that the welfare of patients should always take precedence over any commercial, financial or personal interests. The biggest concern for consumers is whether or not their medical professional is operating in their best interest – free from any influence from pharmaceutical and manufacturing companies and seen to be free of influence.

Health Issues Centre suggests providing more specific guidance to health professionals around the process of dealing with dualities and actual conflicts of interest. This would help avoid confusion and assist health professionals, thus their organisations, to develop clear processes around responding to conflicts of interest and perceived conflicts of interest. Apart from this, we support the recommendations by RACP as we recognise the importance of preserving public trust in the medical profession to provide safe and quality care to patients.

## Entertainment and hospitality (3.2.3)

From a consumer perspective, Health Issues Centre is in broad agreement with this provision. The only comment we would add is regarding the need to provide more guidance on what constitutes "significant educational value" and "lavish dinners and entertainment". For example, would \$10 per person for hospitality at a pharmaceutical drug education presentation be considered appropriate and, if so, what would be considered lavish? Community interpretation of "lavish" might be very different to the definition within the industry. Our response here is strongly based on the idea of potential to influence through repetition of small transfers of value such as regular lunches to one medical practice.

Without wanting to overcomplicate the system, we cannot ignore that the main aim of the guidelines is for consumers to feel confident that their healthcare professionals are making decisions independent of any external influences by for-profit organisations. One potential solution is for medical practices and professional societies to record payments or transfers of value of an agreed value (e.g. \$10 or more) and report publicly all payments or transfers of value of \$100 or more. In this way, consumers are aware of the relationship their medical professional or health-based organisation has with industry and the potential for influence.

### **Drug samples, including starter packs (3.2.4)**

The question of starter packs is one that we find something of a grey area. We appreciate the benefits of starter packs in allowing health professionals to provide treatment promptly and in some cases alleviate some of the treatment cost and, are fully aware of the downside to consumers missing out on these benefits if health professionals choose not to accept drug samples. However it is Health Issues Centre's view that while the benefits of starter packs accrue to the consumer, the bigger potential problem with these is the influencing of prescribing patterns. Given the concern among consumers about influence, overall we would endorse the recommendation that accepting drug samples, including starter packs from industry pharmaceutical representatives is inappropriate.

### **Patient support and educational programs (3.2.5)**

Health Issues Centre appreciates the focus of attention on the issue of industry offering "support" programs to patients such as telephone help-lines and educational websites. We believe there is significant potential for these programs to be used as a way of influencing the attitudes of patients and their doctors to use that company's medications and devices.

We agree that industry representatives of pharmaceutical companies and device manufacturers should not have any direct involvement in patient care; any invitation to participate in industry "support" programs should always be directed at the healthcare team. More importantly, we agree that practitioners should first consider if the program will significantly improve their patient's health and wellbeing outcomes and if yes, critically evaluate whether the information presented is accurate and appropriate.

The main caveat, however, would be that this recommendation would no longer apply if the clinician has a prior or existing relationship with the company or manufacturer of the "support" program they are intending to refer their patient to. If this is the case, it is essential that the patient is fully aware that their practitioners may be subject to influence or bias as a result of their associations with industry. In addition, we believe it is necessary for health professionals and their health services to develop processes to evaluate the long term sustainability and appropriateness of such "support" programs for consumers.

### **Where support is offered to a practitioner not making a formal contribution to a scientific meeting or conference (3.3.3)**

Health Issues Centre wholly agrees with this provision. The biggest concern of consumers with non-presenters accepting industry support to attend conferences is the potential to influence future decisions regarding a sponsor's product. Health Issues Centre believes that whenever there is potential benefit (and, thus influence), health professionals should be required to seek agreement from appropriate institutional committees, declare this publicly for the benefit of consumers and be aware that their acceptance of sponsorship by industry can influence their decisions around patient care.

## Endorsements and “advertorials” – patient access programs and consumer groups (3.4.4.)

Health Issues Centre agrees with the RACP that physicians should not endorse specific products or participate in “advertorials”. The reality is, consumers look to their healthcare team for direction in terms of medication use and health information. If health professionals use their status to promote commercial interests that do not support the welfare of the community and of individual patients, this could lead to *avoidable* health risks associated with the use of unsubstantiated medication or devices and, thus severely damage the trust consumers place in the medical profession.

## Training program (4.6.1)

In general, Health Issues Centre agrees with this provision and emphasizes the need for adequate measures to be taken by organisers to ensure education programs paid by commercial sponsors are free from the possibility of any bias. As suggested by the RACP guidelines, industry sponsors should have no role in designing or selecting speakers or attendees for the educational program.

## Endorsement of other publications or materials produced by outside organisations (4.7.4)

It is Health Issues Centre’s view that it is not necessary to include more specific guidelines and recommendations in section 4.7.4. It would seem more practical for institutions and professional societies to develop policies and processes relevant to their needs and context. The only other comment we would make is around the potential to involve consumers in the process of evaluating external publications and materials for endorsement. Involving consumers not only preserves public trust regarding adequate disclosure and management of interests by institutions and professional societies, but more importantly, the involvement of consumers ensure that publications or materials educating consumers are relevant and genuinely meet the health needs of the community.

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