NZMA
New Zealand Medical Association

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Dear Michael

Doctors and financial conflicts of interest

Thank you for the opportunity to comment on this matter. As you are aware the New Zealand Medical Association (NZMA) takes a strong interest in matters such as this and we have included robust guidelines on this in our Code of Ethics which was reviewed in 2008. The NZMA is pleased however that the Medical Council of New Zealand (MCNZ) is reviewing its statement and we hope that our comments are of use. In preparing our comments we have looked at both the ethical statements the Medical Council has referred to, as well as the following ethical guidelines:

- NZMA Code of Ethics
- Charter on Medical Professionalism (The Lancet and the Annals of Internal Medicine Feb 2002)
- World Medical Association (WMA) Declaration of Lisbon on the Rights of the Patient (2005)
- WMA International Code of Medical Ethics (2006)
- WMA Declaration of Geneva (1995)
- WMA Statement Concerning the Relationship between Physicians and Commercial Enterprises
- WMA Declaration of Helsinki (2010).

Our responses to the questions raised are set out below.

Are standards advising doctors how to handle financial conflicts of interest necessary?
The NZMA believes they are.

Do you agree with the Council that the current standards need to be revised and strengthened?
The NZMA is pleased that the Council is taking the opportunity to revise the guidelines. We are not sure that they need to be strengthened, rather it is a situation of making sure the guidance is clear and covers all potential situations.

Are there any circumstances where it would be acceptable for a doctor to accept a gift, funding or hospitality from a health related commercial organisation (HRCO)?
The NZMA believes there are.

If "yes", under what circumstances, and what standards should be in place to mitigate the influence such gifts, funding or hospitality might have on the doctor's prescribing and treatment decisions?
There are two different situations covered here. Turning first to the question of gifts the NZMA finds the statement by the WMA concerning the Relationship between Physicians and Commercial Enterprises ("the statement" or "WMA statement") to be particularly useful.

> "Physicians may not receive a gift from a commercial entity unless this is permitted by law and/or by the policy of their National Medical Association and it conforms to the following conditions:
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> 1. Physicians may not receive payments in cash or cash equivalents from a commercial entity.
> 2. Physicians may not receive gifts for their personal benefit.
> 3. Gifts designed to influence clinical practice are always unacceptable. Promotional aids may be accepted provided that the gift is of minimal value and is not connected to any stipulation that the physician prescribes a certain medication, uses certain instruments or materials or refers patients to a certain facility.
> 4. Cultural courtesy gifts may be received on an infrequent basis according to local standards if the gift is inexpensive and not related to the practice of medicine."

In our view the key points from the statement are that: the gift is of minimal value, is not designed to influence clinical practice, is not for personal benefit, nor is it for cash or cash equivalent.

Turning next to conference funding both in regard to funding for the conference itself, and for assistance to individuals, for example with costs associated with travel to the conference; in an ideal world the NZMA considers that funding provided by HRCOs for conferences should be channelled through an independent third party. In terms of independence we mean that the HRCO is independent both of any control of the content of the conference or individuals attending the conference, and of the Government. The NZMA considers that it is important that the medical profession itself regulate matters of this nature.

In 2002, courtesy of the BBC, Onora O'Neill a Professor of Philosophy at Cambridge, teacher, bioethicist, philosopher and politician gave a series of five Reith lectures on "A question of trust." Onora O'Neill argued that the "new" accountability may not enhance the quality of professional services in health and education. Trust, she said, is necessary in all our interactions, and is a basic social commodity. She suggests that the basis of a more intelligent accountability is the support of good internal governance rather than "Herculean micro-management."

However, while ideally a doctor should never receive funding directly from an HRCO, that position is impractical in New Zealand in respect of overseas conferences and may mean that

New Zealand doctors are unable to attend overseas conferences which are costly to travel to. The NZMA believes that this is because conference organisers who are given the opportunity to choose who should receive funding, may choose to give the money to other doctors such as those from third world countries or doctors with whom they have a closer affiliation.

Nonetheless this is an issue that the NZMA believes the MCNZ should consider carefully. Key principles whenever funding is provided by an HRCO are transparency and independence.

Are the standards proposed by the Council in relation to medical education appropriate?
The NZMA considers that what guidance is available is acceptable but it could be enhanced. In regard to this, we draw the Council's attention to the WMA's statement as it pertains to medical conferences. That statement sets out a number of points of value that the Medical Council might consider adopting. The relevant section provides the following.

> "Physicians may attend medical conferences sponsored in whole or in part by a commercial entity if these conform to the following principles:
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> 1. The main purpose of the conference is the exchange of professional or scientific information.
> 2. Hospitality during the conference is secondary to the professional exchange of information and does not exceed what is locally customary and generally acceptable.
> 3. Physicians do not receive payment directly from a commercial entity to cover travelling expenses, room and board and the conference or compensation for their time unless provided for by law and/or the policy of their National Medical Association.
> 4. Physicians may not accept unjustified hospitality and may not receive payment from a commercial entity to cover room and board for accompanying persons.
> 5. The name of a commercial entity providing financial support is publicly disclosed in order to allow the medical community and the public to assess the information presented in light of the source of funding. In addition, conference organizers and lecturers disclose to conference participants any financial affiliations they may have with manufacturers of products mentioned at the event or with manufacturers of competing products.
> 6. Presentation of material by a physician is scientifically accurate, gives a balanced review of possible treatment options, and is not influenced by the sponsoring organisation.
> 7. A conference can be recognised for purposes of continuing medical education/continuing professional development (CME/CPD) only if it conforms to the following principles:
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> 7.1 The commercial entities acting as sponsors, such as pharmaceutical companies, have no influence on the content, presentation, choice of lecturers, or publication of results.
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> 7.2 Funding for the conference is accepted only as a contribution to the general costs of the meeting."

Declaring a conflict of interest may ensure transparency, but it will not necessarily mitigate the undue influence that a sponsored continuing professional development event may have on the behaviour of doctors who attend. Should there be additional requirements on doctors in this situation? If so, what should those requirements be?
The points made above by the WMA regarding conferences offer the following additional points that you may wish to include in your guidance.

- The main purpose of the conference is the exchange of professional or scientific information.

- The name of a commercial entity providing financial support is publicly disclosed as is any financial affiliation the conference or conference organisers or lecturers have with the commercial entity.
- Presentation of material by a physician is scientifically accurate, gives a balanced review of possible treatment options, and is not influenced by the sponsoring organisation.

The NZMA also considers that the point made by the Canadian Medical Association about the requirement where possible to use generic rather than trade names in the course of CME/CPD activities is pertinent.

Are the proposed standards relating to the provision of care and advice appropriate?
The NZMA believes they are. Something however should be included on physician endorsement of commercial products. The NZMA developed the following policy statement in 2007.

> **Commercial endorsements**
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> 1. Doctors should avoid any appearance of potential influence on their decision making or judgment on behalf of patients by personal commercial imperatives or commercial interest in products they are endorsing.
> 2. Doctors must declare as part of the endorsement, any commercial interest in the product and state why they are endorsing it. For instance, if a Doctor is deriving financial or other benefit directly or indirectly for appearing in an advertisement or advertorial, this must be stated as part of the Doctor's endorsement.
> 3. Doctors should endorse products using the proper chemical name for drugs, vaccines and specific ingredients, rather than the trade or commercial name.
> 4. Any endorsement should be based on specific independent scientific evidence, and that evidence should be clearly stated.

In some communities it may be difficult for a person who is financially dependent on a doctor (such as a pharmacist) to make a complaint about unethical conduct. How can the Council ensure that doctors do not exploit those who are dependent on them for income?
The NZMA does not have any suggestions in regard to this.

Are the proposed standards relating to research appropriate?
The NZMA believes the standards are appropriate but inadequate. As a minimum the NZMA considers the Medical Council needs to refer to the Declaration of Helsinki, and should elaborate on the issue of ensuring that negative results are made available. The WMA statement on research takes may be helpful in regard to this. It provides the following.

> A physician may carry out research funded by a commercial entity, whether individually or in an institutional setting, if it conforms to the following principles:
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> 1. The physician is subject only to the law, the ethical principles and guidelines of the Declaration of Helsinki, and clinical judgment in performing research and does not allow himself or herself to be subject to external pressure regarding the results of his or her research or their publication.
> 2. If possible, a physician or institution wishing to undertake research approaches more than one company to request funding for the research.

3. Identifiable information about research patients or voluntary participants is not passed to the sponsoring company without the consent of the individuals concerned.
4. A physician's compensation for research is based on his or her time and effort and such compensation is in no way connected to the results of the research.
5. The results of research are made public with the name of the sponsoring entity disclosed, along with a statement disclosing who requested the research. This applies whether the sponsorship is direct or indirect, full or partial.
6. Commercial entities do not suppress the publication of research results. If results of research are not made public, especially if they are negative, the research may be repeated unnecessarily and thereby expose future participants to potential harm.

Are the proposed standards relating to doctors involved in the governance, management, operation and promotion of HRCOs appropriate?
The NZMA believes so. However, we like the clarity of the points made in the WMA statement in its section on Affiliation with Commercial Entities.

> A physician may not enter into an affiliation with a commercial entity such as consulting or membership on an advisory board unless the affiliation conforms to the following principles:
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> a. The affiliation does not compromise the physician's integrity.
> b. The affiliation does not conflict with the physician's obligations to his or her patients.
>
> Affiliations and/or other relationships with commercial entities are fully disclosed in all relevant situations such as lectures, articles and reports.

Relationship between doctors and HRCOs
We trust that the above answers the specific questions you have raised. There is however, a further matter that has been overlooked in this discussion which we draw to your attention. That is the necessity of there always being some relationship between doctors and HRCOs.

Over the years there has been a constant development in pharmaceutical therapy and medical technology; so much so that a therapeutic approach that was up-to-date 40 years ago, today may be seen as malpractice. It would be absurd to believe that today the world has reached an endpoint and we have the final answers. In consequence this means that the world still needs to continue innovating.

Pharmaceutical and technological development has been driven, made and paid for by private companies. Few big drug developments have been brought to the market out of the public domain. This is not to diminish or to devalue the work of those in public research and institutions, but it takes much more than basic research to bring a product to the patient.

If those facts are accepted, then it must be acknowledged that pharmaceutical companies need to be able to market their products. Otherwise development will not happen, because investors will bring their money to other parts of the economy. Advertising, directly and indirectly is a method of communication to bring goods to a market. This is quite legitimate, although many countries correctly limit the public advertising of prescription-bound drugs. (As an aside, while New Zealand doesn't provide any such limits, the NZMA's long standing position is that we should).

If companies cannot communicate their products to the medical profession, the profession will not know of these products and it will be up to the Government to decide whether they should know about them, and whether they can prescribe those products. In the NZMA's view this would not be an acceptable situation.

It is necessary to understand that having interests and promoting them is a basic freedom in a society provided that it is not at the expense of others. The question is not whether an HRCO tries to influence a doctor (this is what politicians do for a daily living) but whether the HRCO tries to exert undue influence on another.

Influencing another doctor to take notice of a new drug is in the NZMA's view not undue, nor is it influencing the doctor to prescribe it when it provides a benefit for the patient or the community. However, influencing the doctor to prescribe despite there being better or more efficient drugs is, in our view, undue influence. In the worst case this may be corruption.

It is important that doctors do not restrict their abilities to build coalitions with whomever the doctors think is necessary. We would not want to see the Medical Council prohibit this. Medical practitioners must be able to talk and to cooperate with all partners in the health care field including companies.

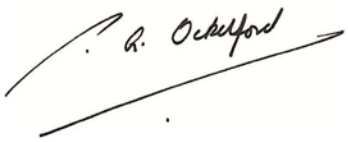
The major principles we should adopt in regard to this are transparency and independence. Transparency is not there to mitigate undue influence although this certainly is a desired side effect. Rather transparency allows a third party to consider whether or not a decision has been influenced. Again the influence may be acceptable, but it also allows us to draw a line.

Independence is the critical point. Independence can best be reached when decisions about therapy can be made independent of outside interests, be they from companies or governments or others. Only then can doctors provide the best care for their patients.

The situation is more complicated with research. This is clearly investor driven. Here the role of the Ethics Committee is to consider not only the clinical and safety issues, but also the business relationship between the sponsor and the participating doctors. Transparency again is crucial to determine whether undue influence is occurring (or has the potential to occur) and should be corrected if so. Finally all clinical research must be registered publicly before it begins and results must be published regardless of the outcome. The NZMA is aware that this challenge has multiple problems with it, but it must be tackled.

We hope that you find our comments useful.

Yours sincerely



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