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Bronwyn Davis
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470 Northbourne Avenue
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Dear Ms Davis

Medicines Australia - Application for Authorisation

We refer to your email of 31 January in which you invited Medicines Australia's (***MA***) response to the submissions received by the Commission in respect of MA's application for authorisation and requested specific advice on a number of particular sections of the MA Code of Conduct (***Code***).

MA's responses to the submissions received by the Commission are set out in section 1 below. MA's responses to the Commission's questions on particular sections of the Code are set out in section 2.

1. Responses to submissions to ACCC

(a) Submission from Dr Ken Harvey

(i) Advertising in electronic prescribing software

MA notes the submission from Dr Harvey and his comments regarding advertisements in prescribing software. MA considers that the fundamental issue is whether advertisements in prescribing software in views other than the clinical tools and patient educational materials should be considered as advertising to consumers or to healthcare professionals. Prescribing software is an electronic tool for doctors. If there is a part of the software that is intended for use directly with patients, MA agrees that there should be no advertisements for prescription medicines. The prohibition in the Therapeutic Goods Regulations is against advertisements that are directed to persons other than healthcare professionals. MA considers that it is legitimate to include advertisements directed to healthcare professionals in media that are primarily intended for healthcare professionals. An analogy is advertisements in print media such as medical journals or other professional print publications, which may also be coincidentally observed by a patient during a consultation if the doctor has the journal in the consultation room. It must be kept in mind that any advertisement for prescription medicines in prescribing software is not intended for, or directed to, a patient.

It is possible that other information may be coincidentally observed by a patient on the doctor's computer screen, such as the names and addresses of other patients from which the doctor picks the particular patient who has presented for a consultation. It is not possible to prevent every possible avenue through which a patient may come across information, but Edition 15 of the Code is designed to prevent the viewing of promotional material through avenues which are intended to be used directly with patients.

(ii) Legibility of generic names

MA agrees with Dr Harvey's comments that the generic name (Australian approved name) should be clearly legible in all advertisements. MA draws the Commission's attention to the amendments included in Section 3.9 of Edition 15 of the Code and the additional guidance included in the Code of Conduct Guidelines, which emphasise the need for all information included in advertisements in prescribing software to be clearly legible, taking into account the "worst case" computer screen resolution that may be in use.

MA does not accept Dr Harvey's assertions that "the main goal of "banner" advertisements … is to promote originator drug brand name reinforcement". The placement of advertisements in prescribing software is equally available to companies that supply the originator brand of a product and to companies that supply other brands of a medicine once it is out of patent. MA also notes that several advertisements reviewed by the Monitoring Committee where the generic name was considered too small and illegible were for brands of medicines supplied by generic manufacturers.

The Code of Conduct Committee has a range of sanctions available to it – from requiring a company to cease using a particular advertisement through to fines of $200,000 and requirement for corrective action. Thus, the Committee may have chosen to impose sanctions within this range. However, after lengthy and proper consideration of the complaint submitted by Dr Harvey, the Committee chose to impose sanctions at the lower end of the scale. MA further notes that the requirement to cease using an advertisement and revise it before re-publication imposes costs on the company which are recognised by the Code of Conduct Committee as part of any sanction. To assist the Commission to further evaluate Dr Harvey's comments, a copy of the minutes of the Code of Conduct Committee's consideration of complaint 801, Advertising in Prescribing Software, is attached (Attachment 1).

MA wishes to also clarify an impression that may be left by Dr Harvey's submission to the Commission in relation to the Monitoring Committee finding "Illegible generic names in a later version of Medical Director software" and the references to "repeated Code breaches" and "multiple proven braches". These comments may give the impression that companies had continued to publish advertisements in prescribing software after receiving advice that some advertisements did not comply with the Code.

Dr Harvey's complaint was submitted to MA in April 2005 and considered by the Code of Conduct Committee over two meetings – in May and June 2005. Advice of the Committee's decisions was provided to all companies in June 2005 at the conclusion of a full consideration of the complaint. In parallel, the Monitoring Committee reviewed a later version of the software (v 2.83) because the version reviewed by Dr Harvey et al (v 2.81) was not available and, more importantly, it was considered more relevant to review the current version rather than a version no longer in use. This review was also undertaken in June 2005. Thus companies would not have had the opportunity to revise advertisements reviewed by the Code of Conduct Committee prior to the Monitoring Committee's review of v 2.83 in June 2005. It is therefore not correct that companies continued to publish advertisements in prescribing software in the knowledge that they did not comply with the Code.

Following the Monitoring Committee's review of all advertisements for prescription medicines included in v 2.83 of Medical Director prescribing software, advice of the Committee's findings was provided to each company. As the Commission is aware, the Monitoring Committee may not itself impose any sanctions on companies but must refer any matter to the Code of Conduct Committee for adjudication (Section 14.4 of Edition 15 of the Code refers). The Monitoring Committee's advice to companies invited them to respond to the Committee stating whether it agreed with the assessment of the advertisements and to give any answer or explanation deemed necessary. If the companies' responses had been considered unsatisfactory, the Monitoring Committee had the option of referring the matter to the Code of Conduct Committee as a formal complaint. However, every company responded that they accepted the Committee's assessment and undertook to withdraw the advertisements found not to fully comply with the Code and make required amendments before publishing any further advertisements. Therefore, the Monitoring Committee did not consider it necessary to refer any matter to the Code of Conduct Committee. In addition, the Monitoring Committee was aware that the Code of Conduct Committee had also considered a particular complaint (complaint 801 from Dr Harvey) concerning advertisements in prescribing software and was therefore dealing with similar matters in parallel.

(iii) Sanctions

Dr Harvey is critical of MA for failing to apply sanctions for multiple proven breaches of the Code. MA wishes to reiterate that that the Code of Conduct Committee has available to it a range of sanctions. Higher sanctions up to a maximum fine of $200,000 apply for breach repetitions (repeating the same breach in promotion of any product) and repeat of a previous breach (the same or similar breach in promotion of a particular product). Thus, the Committee has the ability to impose higher sanctions if it considers that a company has repeatedly failed to comply with the Code.

However, in counterbalance to the capacity to impose higher sanctions is the recognition that each complaint is dealt with on its own merit. It would be a denial of natural justice and an exhibition of prejudice to impose a very heavy sanction for

a relatively minor matter simply because other complaints had been submitted against a particular company without assessing the full circumstances. (Such an approach might also discourage companies from achieving resolution through intercompany dialogue because by not accepting resolution offered by the subject company the complainant might hope to obtain a greater punishment if the complaint is forwarded to the Code of Conduct Committee). MA submits, as evidenced by the Annual Reports of the Code of Conduct Committee, that there is no evidence of companies flagrantly repeatedly breaching the Code. For these reasons, MA believes that the response is appropriate.

(iv) Prescribing practices

MA wishes to reiterate its previous comments to the Commission in response to Dr Harvey's and others' assertions that the "Code encourages inappropriate demand and prescribing … which is often not in accord with cost-effective best-practice". The Code (Edition 14 and the revised Edition 15) includes specific requirements for companies to clearly communicate to healthcare professionals the PBS listing restrictions for a medicine. A medicine may not be listed on the PBS unless it has met certain cost-effectiveness criteria, which are assessed by an independent committee, the Pharmaceutical Benefits Advisory Committee. Thus promotion of medicines within the terms of their PBS listing cannot be claimed to be contrary to "cost-effective best practice". As advised to the Commission in our letter dated 9 January 2006, companies are required to include PBS listing information in all advertisements that include a promotional claim.

(v) Adequacy of self-regulation

Dr Harvey's submission suggests that the extent of the provisions of the Code is not adequate. MA's response to this is that the Code is not legislation, rather, it is a self-regulatory code adopted voluntarily to provide additional guidance on the requirements imposed on pharmaceutical companies. As such, MA aims to achieve a balance between the interests and concerns of pharmaceutical industry participants and the interests and concerns of healthcare professionals and consumers, in a way that assists pharmaceutical companies to comply with their obligations under the *Therapeutic Goods Act* 1989 and their obligations under Part V of the *Trade Practices Act* 1974. As set out in MA's submission in support of its application for authorisation, the Code contributes substantial benefit because of the fact that it provides an additional avenue of complaint, it is easier to access than the Court system and less costly.

(b) Submission by the Australian Consumers' Association

MA is concerned that many of the comments and criticisms of the Code made by the Australian Consumers' Association (***ACA***) in their submission to the Commission are referenced to articles and publications that either do not relate to the Australian environment or quote comments that were made by third parties in relation to Edition 14 of the Code. MA submits that Edition 15 of the Code includes improvements and amendments that address many of the issues raised within the ACA submission.

(i) Monitoring Committee

The ACA contends that the Code is vague in defining the monitoring procedures. This comment is quoted from a journal article by J Lexchin, which in fact refers to Edition 14 of the Code.

Edition 15 of the Code of Conduct has been revised and includes the details that were formerly in Appendix 3 of Edition 14 within Section 14 of the Code. MA considers that the Code provides considerable detail on the procedures by which promotional materials are selected for review (Section 14.1).

The Monitoring Committee's aims are: *to encourage compliance with the Code of Conduct, provide advice on compliance where necessary, obtain and publish statistical data on the rate of compliance and to provide an ongoing mechanism for the identification of potential future amendments to the Code of Conduct.*"

At each monthly meeting the Monitoring Committee reviews the materials against the relevant sections of the Code. As explained in previous submissions to the Commission, since Edition 14 of the Code has been in effect, the Monitoring Committee has reviewed promotional materials in six therapeutic categories in addition to invitations to company sponsored educational meetings, competitions for healthcare professionals, market research activities, company websites and advertisements in electronic prescribing software across all therapeutic classes.

Contrary to ACA's assertion that companies can select which advertisements the will submit for review, the MA secretariat determines which therapeutic area and type of promotional material or activity will be reviewed, ensuring as many therapeutic areas are covered as possible and all different types of promotional material. Further, the Association Representative of each company (who is usually the Managing Director) is required to provide a signed declaration that the material supplied constitutes all the selected material for the product area to be reviewed. In addition, the Committee's review of invitations to company sponsored educational meetings covers all invitations issued over a three month period, which is determined by the MA secretariat and not disclosed in advance to companies.

(ii) Transparency

Once again the ACA comments in relation to the processes of the Code lacking transparency are quoted from the Lexchin journal article, which relate to Edition 14 of the Code, not Edition 15. MA has made a number of changes to the sections of the Code relating to reporting of outcomes in Edition 15.

Although not required by the Edition 14 of the Code, MA currently publishes information about finalised complaints every six months on the MA website, in addition to publishing this information in the Annual Report as required by the Conditions of Authorisation of Edition 14. Complaints about activities directed to consumers are published as soon as the complaint is finalised (ie when the time for appeal has expired or any appeal is concluded), also on the website. In Edition 15 of the Code it is stated that MA will publish Code complaint outcomes quarterly rather than six-monthly on the website whilst continuing to publish information

about consumer directed activities as soon as the complaint is finalised, and in the Annual Report. MA submits that it would be an abuse of process, and unfair to a subject company, if information were to be released about a complaint before the complaint was finalised.

The former Section 16.2 of the Code stated that MA will contact relevant companies before releasing information. This is the source of the comment by Lexchin , which was quoted by the ACA in questioning what would happen if a company refused to have information released. This section is no longer included in Edition 15. As the publication of Code results is a requirement of the Code, a company cannot refuse to have information relating to complaints published.

(iii) Generic equivalents

The ACA also suggests that companies should be required to "name the generic equivalent of their brand new drug", which once again is referenced to the Lexchin article. The relevant statement in the Lexchin article actually refers to the Canadian Code of Conduct, but MA believes the point being made by ACA here is that the generic name (Australian Approved Name) should be included on promotional materials. The MA Code (Edition 15, the 14th edition and many previous editions) requires that the Australian Approved Name of the active ingredient(s) must be included in all forms of promotional materials. Essentially, wherever the brand name appears, the Australian Approved Name must also appear adjacent to the Brand Name, including on small items used as Brand Name Reminders.

(iv) Sanctions

MA disagrees with the ACA's assertion that the sanctions under the Code are nominal. As previously advised, the level of fines provided for in Edition 15, the effect on companies and the cost to them of corrective advertising are comparable with penalties and sanctions imposed under State fair trading laws and the TPA for misleading conduct and other Part V breaches. The sanction that is of most concern to companies and most efficient to communicate to health care professionals is corrective advertising or letters. The Committee is much more likely to require this type of sanction both to ensure any incorrect messages are corrected and to increase compliance with the provisions of the Code. This action and the withdrawal of material all have significant financial implications for the company involved.

(v) Time taken to resolve complaints

The ACA also refers to the time taken to resolve complaints suggesting that companies can continue activities until the complaint is finalised. This is not correct. The times reported in the Code of Conduct Annual Report reflect the time from receipt of a complaint until any appeal is finalised. In 2004-2005, the average time to resolve complaints that were not appealed was 28 days, which is less than a month. For those that were appealed, the average time was 72 days.

However, it must be noted that if a company is found in breach of the Code by the Code of Conduct Committee it must cease the activity found in breach as soon as it receives the Committee minutes, which is within 10 working days following a Committee meeting. If a company elects to appeal against a decision it cannot recommence the activity found in breach until the appeal has been heard and been upheld (Section 11.1.3 refers). Thus, in the time between receiving the Committee minutes and the finalisation of an appeal, the company cannot recommence any activity found in breach.

(vi) Advertising to consumers

It is most unfortunate that the ACA bases its arguments in relation to advertising to consumers on articles that are referring to countries other than Australia, and particularly the US. MA considers that it is a very significant difference between the Australian and US markets that direct to consumer advertising is specifically prohibited in Australia, whereas it is permitted in the US. In quoting once again from the Lexchin article in claiming that the MA Code is "deliberately vague", the ACA appears to be unfamiliar with the considerable detailed and specific provisions of Edition 15 of the MA Code.

Section 9 of the Code deals with the different ways in which the industry can interact with members of the general public, including:

- Responding to enquiries or requests for advice;
- Media statements;
- General media articles;
- Patient education;
- Use of the internet, websites; and
- Patient support programs.

Section 9.4 is quite specific in stating that prescription medicines may only be promoted to healthcare professionals and any activity directed to the general public which encourages a patient to seek a prescription for a specific prescription-only medicine is prohibited. These provisions are supported by a clear definition of promotion which is also quite broad in the activities captured. MA also submits that the Code is significantly more prescriptive than the general prohibition on advertising of prescription medicines to the general public contained in the Therapeutic Goods Regulations.

In relation to the examples of activities which ACA suggests are mechanisms for advertising to consumers, MA offers the following comments:

- It is legitimate for a company to provide educational material to the general public about a therapeutic area or medical condition as long as the material does not discuss specific treatments nor encourage consumers to seek a prescription for a particular product.

- It would be a breach of the Code if a company issued a product-specific media statement that went beyond an educational message and was promotional.
- It is legitimate and consistent with the Code for companies to sponsor consumer support groups and other health consumer organisations. However, it would not be consistent with the requirements of the Code for the sponsoring company to use such sponsorship as a mechanism to encourage consumers to seek a prescription for a particular prescription medicine. MA notes that the Healthy Weight Taskforce referred to by the ACA was dealt with by the Code of Conduct Committee in March 2003 and the sponsor company was found in breach of the Code. The details of this complaint (complaint 693) may be found in the 2003 Code of Conduct Annual Report.
- It would be a breach of Section 9.2 of the Code for a pharmaceutical company to sponsor a medical expert to make statements to the general public that promoted particular medicines.
- MA does not agree that sponsorship of journalism awards would be contrary to the Code. However, sponsorship or payment to a journalist in order to achieve media stories about particular medicines would be in breach of the MA Code and the Media Alliance Code of Ethics.

(vii) Pharmaceutical company representatives

The basis for the ACA's assertion that pharmaceutical company representatives encourage non-rational prescribing is unclear to MA. No evidence is provided to support this assertion. It is a fundamental tenet of the Code, expressed in several subsections of Part 1 of the Code, that all promotion must be balanced, accurate, correct and fully supported by the Therapeutic Goods Administration (***TGA***) approved Product Information.

(viii) Continuing Education Program

In relation to MA's Continuing Education Program, the ACA asserts that MA lacks transparency because it would not provide a copy of the medical representatives training manual. There is a cost for medical representatives to undertake the Continuing Education Program (***CEP***), reflecting the cost of development of the course content and administrative costs of conducting the program. It is reasonable for MA to protect the intellectual property it has created in the course materials. It would therefore be unreasonable to expect MA to distribute the course materials to people who are not undertaking the course. However, general information about the course content and the cost of undertaking it is accessible from the MA website or the University of Queensland Health Institute website. The ACA was directed to this site when it enquired about the course and cost of undertaking CEP.

(ix) Conflicts of interest

Edition 15 of the Code, and previous editions, recognises the importance of providing prescribers with balanced, accurate and correct information because health professionals are making decisions that will impact on a person's health and well being. Pharmaceutical companies have enormous information resources available to them about the medicines they have researched and developed, often gathered over more than a decade prior to the medicine reaching the market. It is an important responsibility of companies to provide objective, scientifically and clinically valid information about prescription medicines to the people who prescribe and dispense these products. The industry recognises there must be a balance between companies' commercial interests and ensuring patients' safety and has therefore developed, implemented and administers the Code and has similarly developed and implemented the training program for medical representatives. Further, recognising that it is not solely medical representatives who should be properly trained, Edition 15 of the Code extends the range of people who are required to undertake the Code of Conduct module to any person who is directly involved in the development, review and approval of promotional materials and educational materials for the general public and any person who directly interacts with a healthcare professional for the purpose of promoting a prescription medicine.

(x) Evidence to support advertising claims

The ACA proposes that use of absolute risk reduction (***ARR***) and number needed to treat (***NNT***) should be mandatory for all advertisements for prescription medicines. This proposal demonstrates a lack of understanding of the nature of these statistical analyses and their applicability to all forms of medicine advertisements and claims.

'Absolute risk reduction' measures the extent to which the selected intervention reduces the risk of an undesirable event or outcome. It is the difference in the rate between the intervention and control group. For example, if mortality from a condition being treated with a new medicine is 20% compared to a 28% mortality with an existing medicine (the control group), the ARR of using the new medicine is 8% or 0.08 (28%-20%). To suggest using this statistic for every medicine would assume that one is always comparing primary outcomes, such as mortality. In many cases, the primary indication of a medicine is not to avoid an undesirable event, but rather to improve a quantitative measurement such as cholesterol or blood pressure. ARR cannot be calculated in such situations since the medicines are compared on the basis of their effectiveness in improving the quantitative measurement (by how much, how quickly, etc) and not on the basis of risk reduction.

Even when the primary indication of the medicine is to reduce the risk of undesirable events, it would not be sensible to mandate the use of ARR in advertisements. ARR is specific to each patient, and is dependent on each patient's underlying risk level. Patients with a higher risk level tend to receive greater ARRs than patients with a lower risk level. Since medicines are usually applicable to patients across a range of underlying risk levels, it is not possible to

quote an ARR that would apply to all patients that could potentially receive the medicine, because to do so would be misleading.

Finally, the ARR for clinical events such as mortality often requires the undertaking of large scale randomised controlled trials in thousands of patients. Mandating the use of ARR in advertisements would effectively mandate the availability of such data, which in some cases will not be possible. Since such data are not mandated for the registration of new medicines in Australia, it would be inappropriate to mandate them in advertising.

'Number needed to treat' is the number of people that would need to be treated, on average, to avoid one additional undesirable event. The NNT is simply the reciprocal of the absolute risk reduction. Therefore, for the above example the NNT with the new medicine for one person to benefit would be 12.5 (1 divided by 0.08). In view of the correspondence between ARR and NNT, the same arguments highlighting the inappropriateness of applying ARR to all medicines also apply to NNT.

(xi) Advertising in Prescribing Software

MA draws the Commission's attention to the comments above in response to the submission from Dr Harvey, as well as to MA's previous responses to submissions from the ACA in relation to advertisements included in prescribing software. The ACA has not commented on the amendments included in Section 3.9 of the Code, which strengthen the Code and limit the placement of advertisements to parts of the software that are intended exclusively for doctors.

(xii) Involvement of consumers

MA has recognised that it is often intimidating or daunting for consumers to prepare and submit complaints about pharmaceutical promotion. It is therefore proposed in Edition 15 of the Code to appoint a panel of Independent Facilitators, as described in section 2.6 below, to assist consumers and other non-industry complainants if they so wish.

MA welcomes opportunities to increase awareness of the Code amongst all stakeholder groups and undertake to work with the ACA, if it would be acceptable to them, to inform their members about the Code.

(xiii) Effectiveness of the Code

The ACA makes a number of assertions relating to the effectiveness of the Code, including that the Code "provides an appearance of regulation but operates so as to permit a range of practices harmful to the public interest." MA does not accept these assertions and notes that there have been a number of submissions to the Commission which point to the effectiveness of the Code and the continuous improvement engaged in by the industry, as further demonstrated by the proposed amendments included in Edition 15.

As explained in previous submissions, the Code includes well-defined restrictions on a company making any false or misleading claims or promoting a product beyond the limitations described in the TGA-approved Product Information.

Further, the Code requires that any claim that will have a significant impact on prescribing must be supported by unequivocal evidence of the highest quality. These requirements are strongly in the public interest as they ensure that prescribers, in particular, receive current, accurate and balanced information from companies to support the quality use of medicines.

As set out above and in MA's submission in support of its application for authorisation, the Code also contributes substantial benefit because of the fact that it is easier to access than the Court system and less costly. This means that complaints can be dealt with quickly and effectively.

(c) Doctors' Reform Society

(i) Difficulty of the process

The Doctors' Reform Society comments that many health professionals and members of the public do not submit complaints because it is too onerous a task and there is a belief that the complaints process is ineffective.

However, MA has in place a number of mechanisms to assist non-industry complainants to participate in the complaints process, and proposes to extend these under Edition 15 of the Code. Non-industry complainants are not required to prepare extensive complaint documentation or argument to support a complaint. MA will accept a brief letter or e-mailed complaint, although every effort is made by the staff of MA to try to obtain sufficient information to allow the subject company to respond to the complaint. To further assist non-industry complainants to develop complaints, or potentially to mediate between a complainant and the subject company if that is their wish, MA proposes to appoint a panel of Independent Facilitators to assist non-industry complainants, as described in section 2.6 below.

In relation to submission of appeals, once again there is no requirement for a non-industry complainant to develop extensive argument. In the interests of natural justice, the complainant may participate to whatever extent they wish in order to argue against an appeal, including having the opportunity to address the Appeals Committee. The Independent Facilitators to be appointed once Edition 15 comes into effect will be available to further assist complainants through this process if they wish to take up this opportunity, at MA's expense.

Further, as noted above and in previous submissions to the Commission, the sanctions available to the Code of Conduct Committee are extensive, ranging from cessation and withdrawal of an activity or materials, requirement for corrective advertising or letters, and fines of up to $200,000. MA therefore disagrees with comments in the submission from the Doctors' Reform Society that the sanctions "amount to almost nothing".

(ii) Membership of the Committees

The Doctors' Reform Society is in error in its statement that the Code of Conduct and Appeals Committees are constructed so that MA has a majority on both Committees. The Commission would be aware that the Code of Conduct Committee's membership is as follows:

- Chairman - Lawyer with Trade Practices experience
- One representative of the Australian Medical Association (***AMA***)
- One representative of the Royal Australian College of General Practitioners (***RACGP***)
- One representative of the Australian Divisions of General Practice (***ADGP***)
- One specialist nominated by the Royal Australasian College of Physicians
- One representative of the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (***ASCEPT***)
- One consumer representative nominated by the Consumers' Health Forum of Australia (***CHF***)
- One representative of the TGA
- Three MA member company Association Representatives
- Two MA member company Medical/Scientific Directors

MA Secretariat staff also attend the Committee meetings to provide administrative support to the Committees and advice, but do not vote on any decisions. On occasion, member company personnel may also attend as observers, but similarly do not vote on any decisions. Thus, if the all MA member company representatives who could attend as full members of the Committee do so, they would number 5 out of the 13 member Committee. MA also wishes to make the Commission aware that for the majority of Committee meetings the Secretariat is unable to secure attendance of the full complement of 5 industry representatives due to the need to avoid any conflicting interests with complainants or subject companies for the complaints to be considered.

Similarly, the membership of the Appeals Committee is as follows:

- Chairman - Lawyer with Trade Practices experience
- One representative from the College and/or Society from the therapeutic class of the product subject to appeal
- One representative from the target audience to which the activity was directed eg: AMA, RACGP, ADGP
- One consumer representative nominated by the Consumers' Health Forum of Australia
- One representative from ASCEPT
- Two MA member company Association Representatives
- One MA member company Medical/Scientific Director

Thus, of the voting members of the Appeals Committee, the full complement of MA member company representatives is three out of the eight member Committee, which is also not a majority.

(iii) Interpretation of the Code

MA disagrees with the Doctors' Reform Society's assertion that the Code is written in vague terms which can easily be interpreted in favour of the industry. The Code is notable for its significant detail compared to other Codes of Conduct within the Australian therapeutic goods industry, the Australian health sector more broadly, or when compared to similar Codes operating in other countries. In addition, as the Commission is aware, the MA Code is supported by the Code of Conduct Guidelines which provide further explanation and interpretation and which are updated regularly in response to queries made to MA regarding the operation of particular sections of the Code and complaints regarding alleged breaches of the Code.

(d) Novo Nordisk

Novo Nordisk submitted to the Commission that there is a possible conflict between the proposed Section 9.4 and Explanatory Note in Edition 15 of the Code and the Therapeutic Goods Advertising Code (***TGAC***) as relevant to devices. The Sanofi Aventis Group also submitted to the Commission that it supported the proposed amendment to Section 9.4 and the Explanatory Note.

In order to clarify this matter and ensure that the MA Code is consistent with the TGAC and the TGA's interpretation of acceptable advertising of medical devices that are used to administer prescription medicines, MA sought further advice from the TGA. Advice was provided on 7 February 2006 from the Acting Director of the TGA Office of Devices, Blood and Tissues and is attached for the information of the Commission (Attachment 2). It is noted that the TGA considers that the inclusion of the words "and can be used to administer products from more than one company" in the Explanatory Note to Section 9.4 imposes too restrictive an interpretation of the TGAC. MA therefore intends to propose to its members that the Explanatory Note to Section 9.4 is amended by deletion of these words.

(e) Australian Nursing Federation

The Australian Nursing Federation raised a number of issues in its submission. However, MA has not dealt with them separately because the issues are similar to those raised in the submissions by Dr Ken Harvey and the ACA.

2. Response to Commission's questions about certain sections of the Code

(a) Product Familiarisation Programs (Section 5.2)

A Product Familiarisation Program (***PFP***) is undertaken by a company to allow healthcare professionals, and particularly prescribers, to evaluate and become familiar with a new medicine or a new use for an existing medicine. Under a PFP a company would make starter packs available to doctors for up to 10 patients to allow them to prescribe the product without cost to the patient whilst gaining an understanding from their own experience of the efficacy and possible side effects of the new medicine. The time in which a PFP can be started following first supply of a new medicine and the maximum duration of

the program are proscribed in Section 5.2, reflecting a reasonable period for doctors to gain familiarity with a new medicine or indication.

In Edition 15 of the Code, the provisions relating to PFP were moved from Section 8 Research in recognition that such programs are not research as usually understood by the industry and health professionals as they occur after a product has been approved for sale by the TGA. Further, recognising that PFPs are not conducted with the same rigor as a clinical research program, it was thought to be inappropriate to collect individual patient data under a PFP. However, aggregated data on a doctor's experience could be collected in order to increase the company's knowledge of the product once it is more widely prescribed. Adverse drug reactions that are spontaneously reported during a PFP would be reported in accordance with TGA requirements.

Additional provisions were also included in the section to emphasise that the purpose of a PFP should be based on a clinical rationale which in turn should determine the number of patients that may be enrolled in a program and how long the program should last in order to develop familiarisation with the product. Further, information should be prepared by the company for the doctor to provide to patients enrolled in the program so that it is clear to consumers why they are receiving the medicine and how long they will receive the medicine at no cost.

MA notes the comments from the Department of Health, South Australia, in its submission to the Commission in relation to continuity of supply of medicines and creating expectations of continued supply. A PFP is, as noted above, intended to allow prescribers to gain familiarity with a new medicine or new use for an existing medicine. Such programs should not be used more widely to supply a medicine outside the normal mechanisms of the Pharmaceutical Benefits Scheme, private prescription or supply through a hospital pharmacy. The industry has been criticised in the past for supplying large numbers of doctors and patients with medicines at no cost in order to gain market share or to exert influence on advisory committees such as the Pharmaceutical Benefits Advisory Committee when considering an application for listing on the PBS. It is in response to these concerns that MA has proposed to include some limitations on the scope of PFPs in Edition 15 of the Code and to emphasise the need for communication of the scope and duration of a program to patients so that inappropriate expectations are not created.

The submission from the SA Department of Health also raises three points concerning the management of PFPs within hospitals. MA submits that these issues are more appropriately dealt with by hospital policies and procedures, potentially guided by advisory groups such as the SA Therapeutics Advisory Groups.

(b) Definition of 'healthcare professional organisation' (Section 7)

A healthcare professional organisation is a college or society representing the interests of its members, such as the Royal Australian College of General Practitioners or the Australian and New Zealand College of Anaesthetists. The Commission's question has highlighted a typographical error in Edition 15 of the Code. As this term is not defined in the Glossary because it is commonly understood, it should not be underlined or asterisked in the Code. This error will be corrected prior to printing.

(c) Description of 'medical practice activities' (Section 7.1.5)

'Medical practice activities' in the context of the Code are activities undertaken within a medical practice, such as a general practice, which are sponsored by a pharmaceutical company. An example might be a diabetes nurse educator, a practice nurse who conducts ambulatory blood pressure monitoring, or a nurse or other qualified health professional who reviews patient medical records and advises doctors on quality use of medicines, clinical monitoring or follow up. The Code Review Panel was aware that companies are more frequently sponsoring such activities within medical practices and was concerned that such sponsorship should not be used as a means to influence prescribers within the practice to initiate treatment with the sponsoring company's products, or switch from another product to the sponsoring company's product. This was the rationale for the changes included in Section 7.1.5 in Edition 15 of the Code.

(d) Patient Support Programs (Section 9.8)

A Patient Support Program is a program run by a pharmaceutical company with the aim of improving compliance by patients (for example, reminding them to take their medicine) and positive health outcomes. Typically the company will develop the program with advice from the health consumer organisation or patient group relevant to the clinical area. Patients are enrolled in the Program once they have been prescribed a particular medicine, have received information about the Program and have agreed to participate.

A Patient Support Program will usually involve providing educational materials for consumers, which are provided to the patient by the healthcare professional who prescribes the medicine. The information and materials are designed to assist consumers to take their medicine safely and appropriately. For example, for a medicine that is self injected, the patient support materials might include instructions and equipment required for safely injecting the medicine, storing the medicine between doses and safely disposing of used syringes and needles. For medicines where it is known that compliance is often poor, the program might include techniques to assist consumers to remember to take their medicine, such as telephone or SMS messages.

It is a requirement of the Code that any Patient Support Program complies with Australian Privacy Legislation. Therefore, each patient must agree to participate after reviewing an explanation of the Program and, if it is part of the Program, agree to receive contact from the sponsoring company. Patients must be free to opt out of the Program at any time.

(e) Membership of the Code Committee (Section 11.2)

The composition of the Code of Conduct Committee has not been changed in Edition 15. However, three changes have been made to the status of certain members or the nominating organisation, as follows:

- The representative of the TGA has been changed from observer to full member. The TGA member has made a valuable contribution to the deliberations of the Code of Conduct Committee and has effectively participated as a full member, except that as an observer the member did not have the right to vote on any decision.
- The nominating body for the member representing a patient support group, with specialist qualifications, has for some years been a single health consumer

organisation. In practice the medical specialist member contributes to the Committee's deliberations from the perspective of a specialist medical practitioner, not as an advocate for a specific group of patients, or patients in general. In consideration that the Committee now includes a consumer representative in their own right, it was thought appropriate to amend the membership of the Committee to specifically include a specialist physician nominated by the recognised national body representing this group of healthcare professionals, the RACP. In addition, on occasion complaints come before the Code of Conduct Committee that deal with activities directed at specialist medical practitioners rather than general practitioners. This further supported the proposal to specifically include a person nominated by the RACP on the Committee.

- The nominating body for the consumer representative was changed from "a recognised national consumer organisation" to the "Consumers' Health Forum" in recognition that the CHF is the national organisation representing health consumers in Australia. CHF's membership comprises approximately 100 health consumer organisations, which in turn represent nearly one million health consumers. CHF is also recognised by the Commonwealth Government as the appropriate nominating body for consumer representatives across a wide range of advisory committees. CHF has demonstrated that it represents consumers nationally and has an active consumer representative program which is based upon a selection process with defined criteria. MA believes that the process undertaken by CHF for nominating consumer representatives to one of the Committees established by the Code is wholly consistent with the principles defined in the guideline "*Principles for the Appointment of Consumer Representatives: A Process for Governments and Industry*" published by the Commonwealth Consumer Affairs Advisory Council. In this guideline, CHF is named as the appropriate consumer organisation to be involved in nominating consumer representatives in relation to health matters (p10).

(f) Appointment of the independent facilitator (Appendix 1)

The advertisement published by MA and description of the services expected to be provided are attached (Attachment 3). The appointment of the panel of three independent facilitators will be made by MA based upon the following criteria:

- experience in dispute resolution;
- knowledge of, or the ability to quickly gain familiarity with the MA Code;
- knowledge and understanding of the Australian pharmaceutical industry;
- limited potential for conflicts of interest with companies subject to complaint or companies or individuals submitting complaints (recognising that it is possible that one facilitator may have a conflict of interest in a particular case, a panel of three facilitators will enable appointment of an alternate facilitator where conflicts arise); and

- it is desirable but not essential that an independent facilitator may have expertise and experience in trade practices law and litigation and be an experienced partner or senior partner in a law firm.

Finally, MA notes the Commission's comments that the Commission will reconsider whether to grant interim authorisation at the draft determination stage, and hopes that interim authorisation will be granted at that time.

Please let us know if you have any further queries in relation to any of the above.

Yours sincerely

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Advertising in electronic prescribing software (801)

Advertising in electronic prescribing software

Complaint
A complaint in the form of a paper submitted to the *Medical Journal of Australia* was received from a healthcare professional alleging that eight pharmaceutical companies were in breach of Section 1.3 and/or Section 3.10, of the Medicines Australia Code of Conduct. The version of Medical Director prescribing software containing the advertisements in question was version 2.81 that was available in November and December 2004.

Response
Letters of response had been received from the following companies:

- Alcon Laboratories (Australia) Pty Ltd (Alcon)
- AstraZeneca Pty Ltd (AstraZeneca)
- Boehringer Ingelheim Pty Ltd (Boehringer)
- GlaxoSmithKline Australia (GSK)
- Novo Nordisk Pharmaceuticals Pty Ltd (Novo Nordisk)
- Pfizer Australia Pty Ltd (Pfizer)
- The sanofi-aventis Group (sanofi-aventis)
- Solvay Pharmaceuticals (Solvay)

Committee Ruling
The prescribing software Medical Director (version 2.83) was projected onto a screen to ensure that all Committee members could view the advertisements in the form they appeared in the software. A demonstration of the way in which Medical Director is likely to be used by a healthcare professional was provided to the Committee. This demonstration was guided by the general practitioners present at the meeting.

The Committee discussed the overall issues relating to the healthcare professional's complaint. GP representatives indicated that the majority of general practitioners were using Medical Director as their prescribing software. It was also noted that there were two alternative electronic prescribing software packages available that do not contain pharmaceutical advertising.

It was also acknowledged that general practitioners are more interactive with their patients than in the past, with the patient sitting alongside them rather than on the opposite side of a desk, and many are using the software within the view of the patient. One general practitioner offered the view that it was up to the doctor to place the screen in a position that was either within view of the patient or ensure that it was turned away if they did not want a patient to view the screen. Another general practitioner commented that occasionally patients do ask questions related to an advertisement such as "What is that medicine used for?". Some members commented that the advertisements were quite subliminal and that often the doctor isn't even aware of what is on the screen. It is possible to pause the advertisement and read it in detail if a doctor chose to do so.

Members used various facilities of the software to check the availability of the PI and references to support claims. It was noted that the references were available by clicking on the 'Notes' button.

Members of the Committee discussed the likelihood that a patient would be influenced to request a prescription for a medicine by seeing an advertisement for a medicine about which they had no knowledge of its use. Members also noted that there were advertisements for other organisations and non-prescription medicines on Medical Director.

Members considered whether it would assist Medicines Australia in its review of the Code in relation to advertising in prescribing software if it undertook some market research with a group of independent general practitioners. It was noted by the Committee that there were only 24

respondents to the healthcare professional's survey and members questioned whether this was actually representative of the views of most general practitioners.

Members were of the view that the complaint must be considered on the basis of each advertisement and its compliance with the Code and not whether advertisements should be allowed in Medical Director.

The Committee suggested that Medicines Australia should write to Medical Director seeking their agreement that they prior to the publication of advertisements in the software due diligence will be taken in ensuring company approval. Similarly companies should put procedures in place to ensure that agencies acting on their behalf communicated with the company in gaining approval for the placement of any advertisement whatever medium.

The Committee also reinforced the view that all companies should undertake some additional education with their staff and agencies to ensure that all advertisements for use in Electronic Prescribing Software are compliant with the Code, particularly the difference between Primary and Short Advertisements. Medicines Australia will also provide further educational messages in their Code newsletter and feedback to companies.

Alcon

Patanol
"Safer and more effective than an ocular steroid"
Alleged breach of Section 1.3 of the Code

Alcon had stated that this was not a false claim as it was supported by published data. However they acknowledged that the comparator product was not registered in Australia and therefore the claim should have been referenced.

The Committee agreed that under the provisions of the Code a claim must be referenced if there is a possibility that a reader may be misled if the source of the reference is not disclosed. The Committee considered that the reference cited to support the claim was an early, limited study which was inadequate to support the general claim. By a majority, the Committee found a breach of Section 1.3 of the Code.

Alleged breaches of Sections 3.10.3, 3.10.4, 3.10.5 and 3.10.6
The Committee determined that "Safer and more effective than an ocular steroid" was a promotional claim therefore the advertisement should be classified as a Primary Advertisement. As the mandatory requirements for a Primary Advertisement were not included in the Patanol advertisement it was found unanimously in breach of Section 3.10.3. As the Patanol advertisement was not classified as a Short Advertisement, Section 3.10.4 was considered not to apply.

Committee members noted that to comply with the provisions of Section 3.10.5 there must be an opportunity to access the references via the body of the advertisement or via a hyperlink or similar mechanism. As stated in the previous section of the minutes references can be accessed by clicking on the 'Notes' button. However in this case the company had acknowledged that they had not provided any references. By a majority the Committee found a breach of Section 3.10.5. In relation to the legibility of the generic name, members unanimously agreed that this was inadequate and found a breach of Section 3.10.6. It was noted that Alcon had acknowledged that the font size was small and that this will be addressed in future advertisements.

Ciproxin HC
"1st line treatment for otitis externa"
Alleged breach of Section 1.3 of the Code

Alcon maintained that Ciproxin HC is approved by the TGA for the treatment of otitis externa without any conditions. Further the Therapeutic Guidelines did not have any regulatory status.

The Committee was in agreement that while most doctors would probably not recommend this treatment as 'first line', there is nothing in the PI to stop a healthcare professional taking this action. Some healthcare professional members of the Committee commented that in indigenous communities it may frequently be used as 'first line' therapy.

By a majority no breach of Section 1.3 of the Code was found.

Sanction
Having found a breach of the Code of Conduct the Committee considered an appropriate sanction.

The Code of Conduct Committee resolved that Alcon should revise their advertisements for Patanol to ensure compliance with the Code.

AstraZeneca

Nexium
"Superior acid control"
Alleged breach of Section 1.3 of the Code

AstraZeneca had responded that the claim was referenced and the published references appear in the advertisement with the qualifying statement appearing, as required by the Code.

The Committee found no breach of Section 1.3 as the claim was qualified as required by the Code and was clear and legible.

Boehringer Ingelheim

Asasantin
"Prevents twice as many strokes as aspirin alone"
Alleged breach of Section 1.3 of the Code

Boehringer Ingelheim had responded that this claim had been found in breach of the Code in January 2005. The appeal against the Committee's finding had not been upheld. Following this outcome all material using this claim had been withdrawn. Boehringer Ingelheim had noted that the complaint was in relation to the version of Medical Director available in late 2004. This advertisement will no longer be used in any publication and will be removed from Medical Director.

The Committee acknowledged Boehringer Ingelheim's response and were of the view that as the company was taking action to have the advertisement removed, no further action should be taken.

Alleged breach of Sections 3.10.3, 3.10.4, 3.10.5 and 3.10.6 of the Code
The Committee determined that "Prevents twice as many strokes as aspirin alone" was a promotional claim therefore the advertisement should be classified as a Primary Advertisement. As the mandatory requirements for a Primary Advertisement were not included in the Asasantin advertisement it was in breach of Section 3.10.3. As the Asasantin advertisement was not classified as a Short Advertisement, Section 3.10.4 was considered not to apply.

Boehringer Ingelheim acknowledged that the relevant reference details were missing from the advertisement and will revise all their materials to ensure compliance with the Code. The Committee found a breach of Section 3.10.5 of the Code.

In relation to the legibility of the generic name, members considered that it was sufficiently legible and no breach of Section 3.10.6 was found.

Sanction
Having found a breach of the Code of Conduct the Committee considered an appropriate sanction.

The Code of Conduct Committee resolved that Boehringer Ingelheim should revise their advertisements to ensure compliance with the Code.

GlaxoSmithKline

Avandia
"Avandia is well tolerated with no clinically relevant drug interactions"
Alleged breach of Section 1.3 of the Code

GSK maintained that the claim was an accurate reflection of the approved PI which states "No clinically relevant drug interactions have been observed with Avandia". In addition the PI states "In clinical trials, adverse experiences with Avandia were generally not dose related, and were mostly mild and transient in nature. In placebo controlled studies, Avandia was well tolerated when used in monotherapy or in combination with SUs and metformin."

The Committee agreed that the claim was not misleading and found no breach of Section 1.3 of the Code.

Avandia
"Avandia helps more patients to achieve HbA_{1C}"
Alleged breach of Section 1.3 and 1.7 of the Code

GSK maintained that the claim was factual and supported by the referenced study.

While some members of the Committee questioned the use of "more patients" in terms of 'more patients than what?' the majority of members were of the view that the claim was supported by the referenced study and found no breach of Sections 1.3 or 1.7 of the Code.

Alleged breach of Sections 3.10.3, 3.10.4 and 3.10.6
Some Committee members were of the view that the tagline "The Next Generation in Glycaemic Control" was more puffery than an actual claim. However it was noted that it was different to statements used in other short advertisements. The Committee referred to the definition of "promotional claim" in the Glossary to the Code where it states "*any statement made by a company which conveys the positive attributes of a product which extends beyond a simple non qualitative or quantitative description of the therapeutic category of approved indication*".

By a majority the Committee found that the statement tended towards promoting the positive attributes of Avandia and therefore should comply with the requirements for a Primary Advertisement. A breach of Section 3.10.3 of the Code was found. As the Asasantin advertisement was not classified as a Short Advertisement, Section 3.10.4 was considered not to apply.

In relation to the legibility of the generic name, members agreed that this could be improved, however in relation to this particular advertisement found no breach of Section 3.10.6. It was noted that GSK had requested further clarification on resolution standards from Medical Director to assist companies when placing advertisements.

Sanction
Having found a breach of Section 3.10.3 of the Code of Conduct the Committee considered an appropriate sanction.

The Code of Conduct Committee resolved that GSK should revise their advertisements to ensure compliance with the Code.

Novo Nordisk

Kliovance, Trisequens and Vagifem
"Controls the lows"
Alleged breach of Section 1.3 of the Code

Prior to discussing the complaint the Committee referred to the Novo Nordisk response which stated that that the process for hearing this complaint was procedurally unfair and that the company had been denied natural justice.

It was the view of the Chairman and Committee that there had been no lack of procedural fairness or reasonable apprehension of bias and that the company had been offered the opportunity to respond to the complaint under the same conditions as all other companies. Therefore the complaint and response should be considered. The Committee also referred to its general comments in relation to complaint 801.

Members considered the complaint under Section 1.3 of the Code.

Novo Nordisk contended that they had not authorised these advertisements to appear in version 2.81 of Medical Director. The Committee commented that Medicines Australia should write to Medical Director seeking their agreement that they prior to the publication of advertisements in the software due diligence will be taken in ensuring company approval of the advertisements. Similarly, companies should put procedures in place to ensure that agencies acting on their behalf communicate with the company for approval for the placement of any advertisement in any medium.

As Novo Nordisk had provided evidence that they had not given approval for the advertisements to be placed in version 2.81 of Medical Director, members were of the view that no breach of the Code could be found.

However the Committee was of the view that they could provide advice on the advertisements in response to the allegation that the claims were false and misleading.

Members were of the view that 'control the lows' was a promotional claim and therefore the advertisements should comply with the requirements for Section 3.10.3 of the Code. The advertisements in version 2.81 of Medical Director did not comply with the provisions for this section. However, as Novo Nordisk had not been invited to respond in terms of this section of the Code, in the interest of natural justice, no breach of the Code was found in relation to Section 3.10.3.

Members were generally of the view that the graphics in each advertisement were consistent with the clinical presentations of menopause eg night sweats, irregular bleeding and vaginal dryness and were not misleading. It was also noted that the clinical presentations were not inconsistent with the approved indications for the products. The Committee was also of the view that it was difficult for Novo Nordisk to respond to the alleged breach when there was no indication of why the complainant thought the claims were misleading. A minority of members were of the view that the claims should be qualified and could potentially be misleading by omission. This minority was of the view that the claim 'control the lows' could be interpreted as meaning 'mood swings' if not qualified. By a majority decision, no breach of Section 1.3 was found.

Pfizer

Norvasc - Ignorvasc and a picture of a brain with a stroke
Alleged breach of Section 1.3 of the code

Pfizer maintained that the picture was not misleading and was appropriately qualified with reference to the statement that it did not imply that patients who did not take Norvasc would have a stroke.

The Committee was of the view that it was reasonable to prescribe an antihypertensive with the purpose of lowering blood pressure and preventing cardiovascular events. Members stated that the association between high blood pressure and stroke is well known. Members also commented that strokes are dramatic by their very nature and therefore did not find the image of the infarcted brain misleading.

The Committee was not of the view that the dramatic visual of an infarcted brain implied the use of Norvasc primarily for the treatment or prevention of stroke and/or myocardial infarction except through the primary indications of blood pressure control and angina. The Committee agreed with the company's argument that there is no disputing the ability of antihypertensive agents to reduce the risk of stroke and myocardial infarction. The Committee found no breach of Section 1.3 of the Code.

Alleged breach of Sections 3.10.3, 3.10.4, 3.10.5 and 3.10.6
The Committee determined that the advertisement implied more than a simple non qualitative or quantitative description of the therapeutic category of approved indication therefore should be classified as a Primary Advertisement. As the mandatory requirements for a Primary Advertisement were not included in the Norvasc advertisement it was in breach of Section 3.10.3. As the Norvasc advertisement was not classified as a Short Advertisement, Section 3.10.4 was considered not to apply.

Committee members noted that to comply with the provisions of Section 3.10.5 there must be an opportunity to access the references via the body of the advertisement or via a hyperlink or similar mechanism. The Committee was of the view that as the references could be accessed by clicking on the 'Notes' button there was no breach of Section 3.10.5.

In relation to the legibility of the generic name, members agreed that there was very low contrast between the generic name and background, rendering the name illegible. A breach of Section 3.10.6 was found.

Sanction
Having found the advertisement to be in breach of the Code of Conduct, the Committee considered an appropriate sanction.

The Code of Conduct Committee resolved that Pfizer should revise their advertisements to ensure compliance with the Code.

Aricept
"Early detection and treatment of Alzheimer's disease with Aricept therapy can maintain independence in daily living"
Alleged breach of Section 1.3 of the Code

In their response Pfizer stated that they did not organise advertising or pay any fees to advertise Aricept in version 2.81 of Medical Director. On investigating the complaint Pfizer had discovered that Medical Director had continued to use this advertisement without the company's authority. Medical Director had acknowledged that they "should have advised Pfizer that the advertisement would continue to be used".

The Committee determined that Pfizer could not be held responsible for the unauthorised use of the Aricept advertisement. The Committee considered that the advertisement was correct at the time it was originally placed in Medical Director as it was consistent with the approved PI. The Committee found no breach of Section 1.3 of the Code.

Celebrex
"A large body of evidence showing no significant increase in cardiovascular risk"
Alleged breach of Section 1.3 of the Code

In their response to the complaint Pfizer stated that they had attempted to remove this advertisement from Medical Director in January 2005 but were unable to do so. Correspondence had been provided in their response supporting this.

Members stated that whilst there had been numerous studies that had addressed some cardiovascular issues in relation to Celebrex, there hadn't been a sufficiently large scale, prospective randomised trial with the primary endpoint of cardiovascular safety. Some members considered that it was misleading to claim that there was a large body of evidence showing no significant cardiovascular risk which implied cardiovascular safety was a primary endpoint in the studies that had been conducted.

There are warnings in the Celebrex Product Information in relation to hypertension, fluid retention and aggravation of heart failure, which are encompassed by "cardiovascular risk". The Committee considered that the claim was contrary to the PI and was therefore misleading and in breach of Section 1.3 of the Code.

The Committee noted that the claim had been found in breach of the Code of Conduct. Whilst acknowledging that the advertisement in Medical Director had been placed prior to any previous finding by the Code of Conduct Committee, members considered the statement was in breach of Section 1.3 of the Code.

Sanction
Having found a breach of the Code of Conduct the Committee considered an appropriate sanction.

Having already been found in breach of the Code for a similar claim the Code of Conduct Committee was of the view that Pfizer should have by now withdrawn the advertisement from use in Medical Director or any other publication as previously directed.

Lipitor
Alleged breach of Sections 3.10.10 and 3.10.11 of the Code

The Code Committee was of the view that while the Code has probably not kept pace with current trends in doctor/patient relations it did not prohibit companies from advertising in electronic prescribing software. Members were not convinced that seeing an advertisement for Lipitor with a tagline "Power you can trust" would stimulate a patient to seek a prescription given that a patient would most likely have no idea of the use of this medicine. The Committee found no breach of Section 3.10.10 of the Code.

In relation to the complaint of preferential placement of advertising (Section 3.10.11), in the absence of a complaint from another company that it had been denied access to placing another advertisement or that Medical Director had refused to place an advertisement in a particular section of their software, this complaint had not been made out.

The Committee urged Medicines Australia to seek clarification from Medical Director on this allegation.

Sanofi-aventis

Stilnox
Helps patients get the right quantity and quality of sleep
Alleged breach of Section 1.3 of the Code

Members were of the view that 'help patients get the right quality and quantity of sleep' was a promotional claim and therefore the advertisements should comply with the requirements for Section 3.10.3 of the Code. The advertisements in version 2.81 of Medical Director did not comply with the provisions for this section. As no complaint had been lodged in relation to this section of the Code no breach was found.

The Committee unanimously considered that the claim was not misleading as it did not go beyond what is in the approved PI and that there was clinical evidence provided in the PI to support the claim. Members noted that the safety issues were addressed in the abridged PI and there was no requirement for these to be included separately in the body of the advertisement. No breach of Section 1.3 was found by a unanimous decision.

Actonel
Alleged breach of Sections 3.10.3, 3.10.4 and 3.10.6 of the Code

Members were of the view that 'you have to act fast to stop one fracture turning into many' was a promotional claim and therefore the advertisements should comply with the requirements for Section 3.10.3 of the Code. The advertisement in version 2.81 of Medical Director did not comply with all the requirements for this section. The Committee found a breach of Section 3.10.3 of the Code.

As the advertisement was found to be a Primary Advertisement and not a Short Advertisement Section 3.10.4 was not considered by the Committee.

Members agreed that the generic name was too small to allow easy and clear legibility as required under Section 3.10.6 of the Code and was therefore in breach of this section.

Sanction
Having found breaches of Sections 3.10.3 and 3.10.6 of the Code of Conduct the Committee considered an appropriate sanction.

The Code of Conduct Committee resolved that sanofi-aventis should revise their advertisements for Actonel to ensure compliance with the Code.

The Committee recommended that the requirements of Section 3.10.7 of the Code should be considered by the Monitoring Committee and the Code Review Panel.

Solvay

Luvox
Clear cut efficacy in depression
Well tolerated
Alleged breach of Section 1.3 of the Code

The Committee was of the view that the claims were not misleading as the current approved PI supported the efficacy of Luvox in the treatment of depression and its tolerability. It was noted that the Primary advertisement included supporting references and the PBS information. Some members were of the view that perhaps it would enhance the information if it was stated that the efficacy was based on studies where the comparators were SSRIs where Luvox was generally well tolerated. It is well known that there is a degree of intolerance in relation to all SSRIs as that is the nature of the

class' pharmacology. Members also commented that perhaps it could state "please refer to the full adverse effects in the PI". However, no breach of Section 1.3 was found as the Committee was of the view that Luvox was well tolerated and efficacious in the treatment of depression within the context of the therapeutic class.

Zanidip
Alleged breach of Sections 3.10.3, 3.10.4 and 3.10.6 of the Code

Members were of the view that 'your first choice CCB' was a promotional claim and therefore the advertisements should comply with the requirements for Section 3.10.3 of the Code. The advertisement in version 2.81 of Medical Director did not comply with the provisions for this section. The Committee found a breach of Section 3.10.3 of the Code. Some members of the Committee also commented that many general practitioners may not know what 'CCB' means.

As the advertisement was found to be a Primary Advertisement and not a Short Advertisement Section 3.10.4 was not considered by the Committee.

Members agreed that the generic name was not sufficiently legible to be easily viewed as required under Section 3.10.6 of the Code and was therefore in breach of this section.

Sanction
Having found a breach of the Code of Conduct the Committee considered an appropriate sanction.

The Code of Conduct Committee resolved that Solvay should revise their advertisements for Zanidip to ensure compliance with the Code.

Attachment 2

18 FEB 2006

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Ms Deborah Monk
Director, Scientific and Technical Affairs
Medicines Australia
Level 1, 16 Napier Close
DEAKIN ACT 2600

Dear Ms Monk,

Thank you for the opportunity to comment on the Novo Nordisk submission to the ACCC in relation to the revised Edition 15 of the Medicines Australia Code of Conduct.

The TGA notes the proposed amendment related to advertising of medical devices in Section 9.4 of the Code and the Novo Nordisk comments. In accordance with the Therapeutic Goods Advertising Code (TGAC), the TGA does not support direct to consumer advertising of prescription medicines and supports Medicines Australia's proposal to limit advertising of devices that are specifically intended to be used with a particular prescription medicine and which carry the name of that medicine.

Nevertheless, it is our view that the amendment to Section 9.4 of the Code of Conduct imposes a very restrictive interpretation of the TGAC requirements and goes further than the intent. We believe that the intent can be achieved without the wording "and can be used to administer products from more than one company".

It would appear reasonable to require that the device must be distributed independently from the active ingredient, and must not be branded with the name of a particular medicine, but can be generically branded for a particular manufacturer's range of products.

Yours sincerely

Phil Harrison
A/g Director
Office of Devices, Blood and Tissues

7 February 2006

Address: PO Box 100 Woden ACT 2606 Website: www.tga.gov.au
Telephone: 02 6232 8444 Facsimile: 02 6232 8605 ABN 40 939 406 804

Attachment 3

Request for Professional Services
Independent Facilitators
Medicines Australia Code of Conduct

Medicines Australia is seeking expressions of interest for the provision of professional services from appropriately qualified and experienced personnel to act as independent facilitators as part of the Code of Conduct complaints process. The closing date for proposals is 20 January 2006.

About Medicines Australia

Medicines Australia is the national association representing the prescription medicines industry in Australia. Our Member companies represent over 90 per cent of the prescription market, and are engaged in the research, development, manufacture, marketing and export of prescription medicines.

Medicines Australia is committed to enhancing the health of Australians by providing medicines of the highest quality, safety and efficacy, and developing new and improved medicines, to which patients should have timely and universal access.

Medicines Australia promotes the interests of the industry by encouraging a favourable investment environment, working on behalf of its members in an advocacy and consultative capacity with government and non-government organisations in Australia and overseas.

Successful Co-Regulation

Medicines Australia's Code of Conduct for advertising and promotion of pharmaceutical products has been internationally recognised for its effectiveness in regulating the marketing and promotion of prescription medicines to health professionals and education of members of the general public.

Adherence to the Code of Conduct is a requirement of membership of Medicines Australia, and non-member companies are also required to comply through a condition of marketing approval of their prescription medicine products.

A copy of the Code of Conduct may be accessed via the Medicines Australia website at www.medicinesaustralia.com.au .

MEDICINES Australia
BETTER HEALTH THROUGH RESEARCH AND INNOVATION

Professional Services required

The new Edition 15 of the Code of Conduct allows the Medicines Australia Board to appoint a panel of three (3) suitably qualified and experienced personnel to act as independent facilitators, for a period of three (3) years.

The independent facilitator may be called upon when a complaint is received by Medicines Australia from a non-industry complainant. In the event that the complaint does not contain sufficient information to allow a company to respond to the complaint, Medicines Australia may contact the complainant and offer the services of the independent facilitator to assist in interpreting any potential complaint in relation to the provisions of the Code or act as an intermediatory with the Subject Company in attempting to resolve the complaint. The facilitator will be required to report back to Medicines Australia on the outcome of any resolved complaint or advise that the complainant wished to take the complaint forward to the Code of Conduct Committee.

The independent facilitators must have:

- experience in dispute resolution;
- knowledge of, or the ability to quickly gain familiarity with the Medicines Australia Code of Conduct;
- knowledge and understanding of the Australian pharmaceutical industry;
- no conflict of interest with the company/ies against which a complaint has been lodged; and
- no conflict of interest with the person or company that has lodged the complaint.

- It is desirable but not essential that an independent facilitator may;
  - have expertise and experience in trade practices law and litigation; and
  - be an experienced partner or senior partner in a law firm.

Lawyers/consultants who act on behalf of a number of pharmaceutical companies may be ineligible for appointment to a panel due to the number of potential conflicting interests.

Remuneration for Professional Services

Remuneration will be provided for the following:

- preparation for meetings including reading time;
- attendance at any meeting or participation in a teleconference with the complainant, Subject Company or Medicines Australia;
- finalisation of the outcomes/minutes following the meeting.

Remuneration will be commensurate with the level of experience.

Submission

Submissions to provide professional services as an independent facilitator should include:

- Curriculum vitae;
- Brief description of previous relevant experience;
- Statement acknowledging potential conflicts of interest;
- Proposed schedule of fees and expenses; and
- If you are part of a firm, consultancy, company you may wish to include brief details of the enterprise.

Please forward two copies of your proposal by 5:00pm on 20 January 2006 to:

Heather Jones
Manager, Marketing Strategies
Medicines Australia
Level 1
16 Napier Close
DEAKIN ACT 2600

For further information please contact Heather Jones at Medicines Australia on 02 6122 8590 or via email at heather.jones@medicinesaustralia.com.au