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Dear Mr Gregson

Medicines Australia – Application for Interim Authorisation

We refer to the public submissions received by the Commission in relation to the application for interim authorisation submitted to the Commission on 30 November 2005 on behalf of our client, Medicines Australia (***MA***). We set out below our client's comments on some of the issues raised in the submissions.

1. Comments regarding extent of the Code

Some of the submissions suggested that the extent of the provisions of the MA Code of Conduct (***Code***) is not adequate. MA's response to these submissions 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 (***TGAct***) and their obligations under Part V of the *Trade Practices Act* 1974 (***TPA***). As a result, MA also refutes the submission that the Code endorses misleading pharmaceutical promotion.

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 is easier to access than the Court system and less costly. It addresses potential breaches of the misleading and deceptive conduct provisions of the TPA through the handling of complaints made to the Code Committee and the operation of the Monitoring Committee.

2. Comments relating to Starter Packs (Section 5)

Mr Petrie of Queensland Health has advised the Commission that he does not believe that the National Coordinating Committee for Therapeutic Goods (***NCCTG***) has finally endorsed the changes MA has proposed relating to Starter Packs. However, MA had understood that the NCCTG has endorsed the changes to the Code with respect to the provisions relating to Starter Packs. The draft Code for the Supply of Starter Packs (which was incorporated into the Code as Section 5) was submitted to the NCCTG in December 2004 and received that Committee's endorsement at its meeting on 26 April 2005.

In consideration of Mr Petrie's submission to the Commission, to clarify the position, MA has sought advice from the TGA about the NCCTG's endorsement of the amendments to the Code relating to Starter Packs.

MA understands that the NCCTG is currently considering the proposed labelling requirements under the Australia New Zealand Therapeutic Products Authority, which are being drafted by an Expert Committee. These draft labelling requirements include provisions relating to the labelling of Starter Packs. The draft Label Order includes requirements relevant to the overall labelling of a starter pack, which, as would be expected in a legislative instrument, are more extensive than the provisions of the Code, which is intended to set standards of conduct in the marketing and promotion of medicines and, with respect to Starter Packs, primarily concerned with appropriate distribution and security during transport.

MA submits that there is no conflict between the proposed requirements in the draft Label Order and the labelling requirements stated in Section 5 of Edition 15 of the Code. In particular, Section 5.1.8 of the Code requires that primary labelling of Starter Packs must comply with the current Therapeutic Goods Order on labelling. As the Commission would be aware, as the Label Order is a legislative requirement, it would take precedence over the Code.

In addition, there is no conflict between the Code provisions relating to Starter Packs and the existing State and Territory legislative provisions concerning these product packs. Until the States and Territories repeal their relevant provisions, there is no detriment from the two requirements existing together. The Starter Pack requirements in the Code are designed to replace some of the provisions in the State and Territory legislation in accordance with the recommendations of the Galbally Review. MA has advised all members and non-members to ensure that they are kept informed of any changes in Commonwealth and State laws concerning the supply of Starter Packs, and this statement is included as the Explanatory Note to Section 5 (introductory paragraphs) of the Code.

3. Comments regarding advertising in Electronic Prescribing Software

Several submissions to the Commission in response to the application for interim authorisation have raised objections to the inclusion of advertisements in prescribing software used by medical practitioners.

The Commission may be assisted with some background to Dr Ken Harvey's complaint in relation to this issue. In April 2005, MA received a complaint from Dr Harvey in the form of

an article that was submitted by Dr Harvey to the *Medical Journal of Australia* which was subsequently published on 18 July 2005. It related to the December 2004 version (version 2.81) of Medical Director prescribing software.

The current edition of the Code (Edition 14) permits advertising in electronic prescribing software (Section 3.10).

Dr Harvey's complaint was forwarded to the independent Code of Conduct Committee for its adjudication along with responses from the individual companies whose advertisements had been identified in the complaint. The Committee is chaired by a lawyer with trade practices experience and currently consists of representatives from the Australian Medical Association (***AMA***), Royal Australian College of General Practitioners (***RACGP***), Australian Divisions of General Practice, Australian Society of Clinical and Experimental Pharmacologists and Toxicologists, a specialist nominated by a patient support group, a consumer nominated by the Consumers' Health Forum, an observer from the Therapeutic Goods Administration (***TGA***) and several Medical or Scientific Directors and Managing Directors from member companies with no conflict of interest in the therapeutic areas subject to complaint.

Dr Harvey's complaint was considered by the Code of Conduct Committee at meetings in May and June 2005 (it took two meetings to consider all the details of the complaint which related to 16 products supplied by 8 companies).

In relation to Dr Harvey's complaints, they fell into three general areas:

- Whether certain claims were misleading – most of these complaints were not upheld. Of those that were upheld (three), two related to claims that had already been considered by the Code Committee in relation to other complaints (about promotional materials other than prescribing software) heard between January and June 2005. The Committee confirmed its earlier decisions in relation to these advertisements in the prescribing software.
- Whether advertisements that contained promotional claims included all the information required for Primary advertisements in prescribing software. A number of the advertisements subject to this type of complaint were not fully compliant through omission of the name of the company, PBS listing statement, a statement that further information was available on request from the supplier, failure to display references or provide a link to references to substantiate claims. It was evident from companies' responses to the complaint that there was misunderstanding that smaller 'banner' format advertisements were still classed as primary advertisements if they included a promotional claim and therefore must include certain mandatory information. This has been further clarified by amendments included in Section 3.9 of Edition 15 of the Code, supported by more extensive explanation and guidance in the Code of Conduct Guidelines to Edition 15.
- Whether the generic name was clearly legible. A number of the advertisements did not meet this requirement. The requirement that the type size used in advertisements in prescribing software should allow easy and clear legibility has

been emphasised by an amendment to Section 3.9.7 of the Code, also supported by further explanation and guidance in the Code of Conduct Guidelines.

Having received the outcomes from the Code of Conduct Committee's decision, the companies found in breach of the Code were required to amend their advertisements. No company appealed against these decisions.

More generally, MA has advised all its members (and non-members) that they must ensure that their advertisements in prescribing software meet the Code requirements for Primary advertisements if they include a promotional claim. This advice was sent to members on 22 April 2005. It has also been reinforced through a Code Newsletter that reports to members on issues raised through complaints.

MA also forwarded Dr Harvey's concerns to the Monitoring Committee for their review. The Monitoring Committee then conducted a review of every advertisement in the then current version of the prescribing software (version 2.83 - Dr Harvey's complaint related to the previous version 2.81 which contained some different advertisements).

At the Monitoring Committee meeting held on 20 June 2005 the AMA and RACGP members expressed their organisations' objections to the presence of advertisements in prescribing software and the possibility that patients may view advertisements for prescription medicines during a medical consultation. However, since the Code currently allows such advertising, the Monitoring Committee reviewed the current version (version 2.83) against the requirements of the Code. Overall the main concerns raised by the Monitoring Committee with respect to compliance with the Code related to legibility of the generic name of some medicines, and failure to include elements of the mandatory information to be included in Primary advertisements such as the PBS listing information, company name, and a link to references for claims.

As a result of the Monitoring Committee's consideration of the issues raised by Dr Harvey, a number of recommendations were provided to specific companies whose advertisements were reviewed. The need to ensure full compliance with the Code in relation to advertisements in prescribing software was reinforced to all companies through the MA Code Newsletter referred to above.

Based on submissions to MA's review of the Code and stakeholder feedback, the provisions relating to advertising in electronic prescribing software have been revised. In particular, the Code now prohibits the inclusion of an advertisement for a prescription medicine **in any clinical tool or patient education materials which may be used by a prescriber for consultation or discussion with a patient**. This provision is intended to avoid patients being exposed to advertisements on the computer screen when the doctor is likely to be using information on-screen to counsel a patient. In addition, requirements relating to the legibility of generic medicine names have been strengthened and the mandatory requirements for Primary advertisements (which are those that include a promotional claim) have been emphasised to companies as explained above.

In addition, MA understands that Medical Director, a major supplier of prescribing software, has removed large format advertisements from the screen displayed whilst a document is printing, which was complained of particularly by doctors and their peak representative bodies – the AMA and the RACGP).

MA considers that electronic prescribing software, which is a tool for use exclusively by doctors, is a legitimate medium for advertising of prescription medicines to appropriate healthcare professionals. However, MA considers that the amendments to the Code relating to advertisements in prescribing software serve to strengthen the Code and assist companies to comply with their obligations under the TGAct, which prohibits advertising of prescription medicines to consumers.

4. Comments regarding the Code Review Process

MA rejects the assertion by Dr Harvey that the Code revision process only involved organisations that have an intimate "and often dependent" relationship with the pharmaceutical industry. MA has provided the Commission with a list of all the organisations that were invited to provide submissions to the review. MA also welcomed submissions from any other party who expressed an interest in providing comments (as is evidenced by Dr Peter Mansfield's own submission to the Commission).

The submission from the Australian Consumers' Association (***ACA***) claims that it was not included in the consultation leading to Edition 15 of the Code. Dr Harvey further asserts that the Doctors' Reform Association (sic) was excluded from the consultation process.

MA wrote to the ACA and Doctors' Reform Society on 27 January 2005 inviting submissions to the review of the Code, but neither organisation chose to take up this opportunity, although the time frame for submissions was extensive – MA was open to comments and submissions throughout the review period of approximately eight months, although MA did request comments be submitted early in the process to provide direction to the review. MA therefore considers that Dr Harvey's and the ACA's criticisms of the Code review process are unfounded.

5. Comments regarding sanctions under the Code

Dr Harvey asserts in his submission that "many pharmaceutical companies repeatedly breach the Code" yet provides no evidence to support this assertion. MA's response to these assertions is two-fold.

Firstly, there are many companies that have not been found in breach of the Code at all, and some that have never had a complaint lodged against them. In relation to companies that have been found to have breached the Code on more than one occasion, MA submits that this is typically the larger pharmaceutical companies which have a wider range of products. However, MA also highlights that the Code provides for significant additional financial penalties in the event of repeat breaches, up to a maximum of $200,000 per breach.

Secondly, 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. Previous research has indicated to the Code of Conduct Committee that the sanction that attracts most attention within the industry and is 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.

In addition, as referred to above, the Code is easier to access than the Court system and less costly and time-consuming. MA submits that many breaches are addressed by the Code of Conduct Committee that would not be addressed by the Court system, and the Code provides an additional avenue by which complaints can be made in relation to the conduct of pharmaceutical companies.

6. Comments regarding inappropriate demand and prescribing of heavily promoted drugs

Dr Harvey also refers to the growing cost of the PBS and claims that the Code "encourages inappropriate demand... which is often not in accord with cost-effective best-practice)". The ACA submission also provides comments on 'leakage' leading to increase costs to the PBS. However, 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.

For example, Section 3 Promotional Material states that all promotional material covered by Sections 3.1, 3.2, 3.3, 3.4, 3.6, 3.7, 3.8, 3.9 and 3.10 must include a clear and prominent statement drawing the attention of the reader to any Pharmaceutical Benefits Scheme (***PBS***) listing and restrictions or its non-availability via the PBS."

These requirements were introduced into the Code as part of the PBS Quality Enhancement Program, which is a measure announced in the May 2002 Federal Budget aimed at supporting the quality prescribing of medicines listed on the Pharmaceutical Benefits Scheme. The PBS Quality Enhancement Program has sought to enhance existing information sources for General Practitioners about the restrictions applying to medicines listed on the PBS (Restricted and Authority Required benefits).

The QEP has been evaluated each year since its introduction by an independent consultant appointed by the Department of Health and Ageing, Healthcare Management Solutions (***HMA***). MA has been informed by HMA that these evaluations have demonstrated a net saving to Government expenditure. HMA has informed MA that the saving is directly linked to companies' compliance with the Code requirements to communicate to healthcare professionals the PBS listing restrictions for a medicine.

7. Comments regarding amendment to Section 9.4 (Promotion to the general public)

Novo Nordisk has 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 as relevant to devices.

The amendment to Section 9.4 and the Explanatory Note in Edition 15 of the Code is intended to address the advertising of medical devices directly to consumers where such

advertising would be equivalent to advertising the prescription medicines delivered by such devices directly to the general public, which is prohibited by the TGAct. Edition 14 of the Code was narrower in that Section 9.4 (Explanatory Note) only referred to insulin delivery devices. There are now more devices available to self-administer a broader range of prescription medicines, such as hormone therapies used in in-vitro fertilisation. The Code Review Panel considered that where a medical device can be used only to deliver one company's medicine or range of similar medicines, such as insulins, this would be equivalent to direct to consumer advertising of prescription medicines. This position was supported by the Acting Director of the Drug Safety and Evaluation Branch of the TGA when MA met with him and other TGA officers in November 2005.

If you have any queries regarding MA's comments above, the submissions made, or in relation to the application generally, please do not hesitate to contact us.

Yours sincerely

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