Thursday, 15 December 2005

Mr Scott Gregson
General Manager Adjudication Branch
Australian Competitive & Consumer Commission
PO Box 1199
DICKSON ACT 2602

Application for revocation and substitution (A90994-6) lodged by Medicines Australia Inc.

Dear Mr Gregson,

Novo Nordisk Pharmaceuticals Pty Ltd values the opportunity to provide a written submission to the ACCC with regard to Medicines Australia's application for revocation and substitution of Edition 14 the Code of Conduct (A90994-6). Please find below our submission for the interim authorisation.

Novo Nordisk applauds the enormous effort of Medicines Australia in providing the next Edition to the Code of Conduct (CoC) as this document is of great value to the pharmaceutical industry. We also applaud the wide stakeholder consultation process undertaken by Medicines Australia and the time taken to develop a document that will hopefully satisfy all stakeholders. Novo Nordisk believes that Edition 14 and the proposed amendments in Edition 15 to the CoC are "effective" in regulating the marketing of prescription products to healthcare professionals.

However, we believe that one particular proposed amendment in Edition 15 may not be "effective" in regulating the relationship between the pharmaceutical industry and the general public (Section 9.4 of Edition 15 with the accompanying explanatory note). We consider that "detriment to competition and/or the public" may result from this specific amendment. We therefore seek ACCC advice as to whether we are correct in our assertion that a possible conflict exists between Edition 15 and the Therapeutic Goods Advertising Code for medical devices (Guidance Document Number 8, version 1.5) and that this proposed amendment may provide a competitive advantage to some suppliers over others, which did not exist with Edition 14.

Novo Nordisk sought advice from Medicines Australia on what we believe to be a possible conflict in the guidelines for promotion of medical devices to the general public. We specifically sought advice as to the rationale behind this amendment, how alleged breaches to Section 9.4 will be handled by Medicines Australia and/or the TGA and asked for comment

about the equity of this amendment across the industry. Novo Nordisk appreciates Medicines Australia's efforts to have it considered by the Code Review Committee but we are concerned that

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the response does not adequately address these issues and fails to resolve the apparent conflict. Any outstanding conflict would impact on the overall "effectiveness" of the revised CoC and therefore, we thought it appropriate to make a submission to the ACCC before the CoC becomes effective in two weeks time.

Included below is the amended text from Section 9.4 of Edition 15 of the CoC, the relevant Therapeutic Goods Advertising Code (TGAC) text on the DTC advertising of devices and comments as to how this proposed amendment to the CoC impacts on the advertising of Novo Nordisk medical devices (as an example). Included in each section is an outline of why we believe this amendment may impact on the "effectiveness" of the revised CoC and why it may be "detrimental to competition and/or the public". Novo Nordisk would suggest that this Section requires revision to resolve any conflict and/or inequities that may be created.

1. Proposed Amendment to Section 9.4 of Edition 14 of the Medicines Australia CoC

The proposed amendment to Section 9.4 of Edition 14 of the CoC that Novo Nordisk wishes the ACCC to consider is the explanatory note to Section 9.4. Specific text which is relevant to this submission is underlined below:

> *"9.4* ***Promotion to the General Public***
> *Prescription products may only be promoted to healthcare professionals. Any information provided to members of the general public must be educational. Any activity directed towards the general public which encourages a patient to seek a prescription for a specific prescription-only medicine is prohibited.*
>
> ***9.4 Explanatory Note***
> *Promotion of a medical device* to the general public is permitted in restricted circumstances. A medical device which is used for the administration of a prescription medicine, including Schedule 3 medicines that are predominantly prescribed by a medical practitioner, that is distributed independently from the active ingredient and can be used to administer products from more than one company, is permitted as long as the medical device is not branded with the name of a particular medicine. The device must be listed with the TGA as a device."*

Section 9.4 with its explanatory note in the previous Edition of the code (Edition 14) specifically exempted insulin delivery devices from this prohibition:

> *"9.4 Promotion of an insulin delivery device* to the general public is permitted."*
>
> **Insulin delivery device was defined as any device used for the administration of insulin but distributed independently from the active ingredient. The device will be listed with the TGA as a device."*

The CoC states that any activity, which encourages a patient to seek a prescription for a specific medicine is prohibited. Novo Nordisk supports this prohibition, however, of most concern is the addition of "from more than one company" to the proposed text.
These points are relevant to our concerns outlined below for the following reasons:

(i) The proposed amendment to Section 9.4 differs from the guidelines provided in the TGAC for medical devices and therefore needs careful consideration before substitution is approved by the ACCC. Transparency around the rationale for the proposed amendment is of paramount importance and needs to be communicated.

(ii) A number of insulin delivery devices registered/listed on the ARTG can be used for the administration of more than one medicine from one supplier. As of 01 Jan 2006 DTC promotion of these devices will no longer be allowed as it satisfies Section 9.4 but not the accompanying explanatory note of Edition 15.

(iii) It is also possible that devices registered/listed on the ARTG can be used for the administration of medicines from more than one company but they are currently not promoted as such and there is no requirement in the CoC to do so. This proposed amendment may inadvertently provide a competitive advantage for these insulin & device suppliers. In this case Novo Nordisk would suggest that any future DTC promotional materials with these devices should emphasise to the lay audience that these devices can be used for the administration of other insulins available from other suppliers as well. Would they be obliged to list them?

Without this stipulation these insulin & device suppliers still benefit from being able to promote the devices and their insulins by default. This is a "detriment to competition" as these devices are not compatible with all insulins available in Australia and therefore only selected insulin suppliers will be able to promote devices DTC.

(iv) Novo Nordisk is aware of one device supplier in Australia with a range of insulin pen devices promoted as being compatible with insulins from more than one company. With the proposed amendment to Section 9.4 of Edition 15 of the CoC, this supplier will be given a competitive advantage in the promotion of these devices over Novo Nordisk and possibly other suppliers. The promotion of these devives also results in the surrogate promotion of medicines from the 2-3 insulin suppliers that these pens are compatible with. With the proposed amendment in place, these devices may be the only type able to be promoted DTC. As above, Novo Nordisk would argue that this is a "detriment to competition" as these devices are not compatible with all insulins available in Australia and selected insulin suppliers will still have a mechanism for surrogate promotion of their medicines over others.

(v) TGA exemptions for DTC promotion of various medical devices under Section 42DF(1) of the *Therapeutic Goods Act* 1989, are in place. How will the validity of these exemptions be affected by the proposed amendment?

2. The Therapeutic Goods Advertising Code (TGAC)

The current Therapeutic Goods Advertising Code describes what medical/therapeutic devices are allowed to be advertised directly to the general public and where TGA approval is required (Section 42DF(1) of the *Therapeutic Goods Act* 1989). This advice is consistent with the explanatory note in Section 9.4 of Edition 14 but not Edition 15 of the CoC (see above). Specifically there is no stipulation that the medical device must be able to administer products from more than one company.

The FAQ page on the TGAC website also provides the following advice: (http://www.tgacc.com.au/)

> *"3. What products may be advertised to the public?*
> *Healthcare products available without prescription from pharmacies, health food stores, supermarkets and by direct marketing can be advertised to the public.*
>
> *4. Do I need formal approval for advertisements?*
> *YES, all advertisements for designated therapeutic goods published for valuable consideration in the following media must be approved. Broadcast: television, radio and cinema*
> *Print: newspapers and magazines (including inserts)*
> *Outdoor: including billboards, bus shelters, bus sides and interiors and taxis displays.*
>
> *5. What advertisements don't require approval?*
> *Advertisements not displayed outdoors, such as indoor posters, leaflets, brochures, catalogues, point-of-sale material, facts sheets, shelf wobblers and the internet do not require formal approval. Nor do advertisements for therapeutic devices. However, they must comply with the Therapeutic Goods Act, Regulations and the Code."*

A therapeutic/medical device is defined by the TGAC as:

> *"...therapeutic goods consisting of an instrument, apparatus, appliance, material or other article (whether for use alone or in combination), together with any accessories or software required for its proper functioning, which does not achieve its principal intended action by pharmacological, chemical, immunological or metabolic means though it may be assisted in its function by such means, but the expression does not include therapeutic goods declared by the Secretary, by order published in the Gazette, not to be therapeutic devices."*

This definition is expanded in the TGA Australian Medical Devices Guidance Document Number 25: Classification of Medical Devices (Jan 2005) to read:

> *"A medical device is:*
> *(a) any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:*
> *(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;*
> *(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;*
> *(iii) investigation, replacement or modification of the anatomy or of a physiological process;*

(iv) control of contraception;

and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or

(c) an accessory to such an instrument, apparatus, appliance, material or other article."

Importantly this definition is consistent with Edition 14 of the CoC in that the device is supplied separately from the medicine and that its principal intended action or function is dependent on the medicine.

How the Amendment to Section 9.4 May Impact on the "Effectiveness" of the CoC

Novo Nordisk has not been able to identify any TGAC requirement for the medical devices to be able to administer medicines from more than one company. Edition 15 of the CoC states that in 2006 all alleged breaches involving DTC promotion received by Medicines Australia will be referred to a central complaints panel (once the new joint agency has been set in place). Medicines Australia is able to refer complaints against non-member companies to the TGA for adjudication, instead of the Medicines Australia Complaint Committee (Section 11.4). Herein lies an important inconsistency - a sponsor may be in breach of the Medicines Australia CoC but not in breach of the TGAC.

The preamble to the Medicines Australia CoC states that"

"This Code of Conduct sets out standards of conduct for the activities of companies when engaged in the marketing of prescription products used under medical supervision as permitted by Australian legislation. The Code owes its origin to the determination of Medicines Australia to secure universal acceptance and adoption of high standards in the marketing of prescription medicines for human use."

Novo Nordisk acknowledges that there is an inherent overlap when considering promotion of medical devices that are used to administer prescription medicines. However, our understanding is that suppliers of devices only are not obliged to follow the Medicines Australia CoC as they do not market prescription medicines but instead they must comply with the Therapeutic Goods Act, Regulations and the TGAC. This difference between suppliers is problematic as the CoC does not therefore have uniform applicability across the therapeutic goods industry. Furthermore, Medicines Australia member companies that supply both devices and medicines will be disadvantaged by this proposed amendment as they need to follow the TGAC etc. but unlike some competitors will be obliged to follow the more restrictive text in Section 9.4 of Edition 15 the CoC for promotion of their devices. This apparent inequity is also important when considering the "effectiveness" of the Code.

3. Impact of the Amendment to Section 9.4 on Sponsors of Selected Medical Devices.

Novo Nordisk is the leading supplier of insulin and insulin delivery devices commonly referred to as insulin pens, for people with insulin-requiring diabetes in Australia. Our range of devices, include both durable and prefilled injection systems. There is a fundamental difference between

the two types and this is important when considering the "effectiveness" of the proposed amendment to the CoC. The following is provided as an example of the impact of the proposed amendment on Novo Nordisk business specifically.

Novo Nordisk insulin pens:

(i) Novo Nordisk prefilled insulin delivery devices are classed as disposable multi-use devices that contain one prescription drug (eg. FlexPen®, InnoLet® and NovoLet®). These devices are supplied prefilled with the medicine, labelled as such, cannot be supplied separately from the medicine and are therefore only available by prescription. Due to this integration of medicine and device they are considered by Novo Nordisk and the TGA as prescription medicines. Novo Nordisk accepts that we are therefore prohibited from advertising the prefilled insulin delivery devices directly to the general public under the TGAC and Section 9.4 of the CoC.

(ii) Novo Nordisk durable insulin delivery devices (eg. NovoPen® series and Innovo®) are by contrast, multi-use devices but not disposable, can be used with any one of seven different Novo Nordisk insulins and are therefore not labelled with any drug name. Importantly, these devices are available directly from Novo Nordisk or alternatively from retail pharmacies and other sources without a prescription. As they are supplied separately from the medicine they are considered as medical/therapeutic devices and not prescription medicines.

Novo Nordisk would argue that our durable device range ((ii) above) is consistent with the definitions provided by the TGA and Edition 14 of the Medicines Australia CoC and would be suitable for direct to consumer promotion (albeit with due consideration of restricted representation requirements). The proposed change to Section 9.4 of Edition 15 of the CoC is in conflict with the TGAC requirements and prevents DTC promotion of these Novo Nordisk and similar devices.

Why Change this Section of the CoC?

Novo Nordisk is puzzled as to the need for this proposed amendment given that Medicines Australia has not made public on its website since 2003, any breaches of Section 9.4 of the CoC related specifically to devices. In one 2004 complaint listed on the website (number 757) the Code Committee noted their concerns about promotion of an IVF drug device to the general public but also acknowledged that the company had approval from the TGA to do so. No breach of this section of the Code was therefore recorded.

> Complaint number 757*: "Members were of the view that while the TGA had granted an exemption for the pen Injector, [branded with the drug name], to be advertised directly to consumers for infertility, any advertisement to healthcare professionals should still comply with the Medicines Australia Code of Conduct."*

TGA exemptions for DTC promotion of other medical devices under Section 42DF(1) of the *Therapeutic Goods Act* 1989 are in place (see below).

As part of the invited stakeholder review process of Edition 15 of the CoC, Novo Nordisk sought clarification from Medicines Australia as to the rationale for this amendment. We were advised by Medicines Australia that:

"the matter of promoting devices has come before the Code of Conduct Committee and the concern has been that companies are promoting devices with prescription medicine names on them which is seen [as] a surrogate for promoting a prescription medicine."

Novo Nordisk agrees with the concern expressed by Medicines Australia but it is important to note that this rationale is relevant to prefilled or drug-labelled devices similar to Novo Nordisk devices described in point (i) above. It should not be relevant to Novo Nordisk devices in point (ii), as they are not labelled with the name of any medicine, can be used with a number of different medicines and they are available without a prescription from retail outlets.

A patient reading an advertisement for a durable insulin delivery device such as NovoPen® or Innovo® for example is not able to seek a prescription for a specific prescription-only medicine, which satisfies Section 9.4. Novo Nordisk supplies seven different medicines (insulins) suitable to be used with these devices. These insulins have different trade names, 2 different active ingredients and importantly different medical applications. The decision as to which insulin (Novo Nordisk or other) to prescribe for a patient with diabetes lies with the physician and is dependent on the diagnosis, the patient's diabetes management plan, their treatment targets and not on the device *per se.*

Novo Nordisk would therefore argue that any conflict in the CoC may impact on its "effectiveness". Medicines Australia has previously noted a potential conflict as part of the CoC Committee ruling in complaint number 757 above:

"After reviewing the definition of 'product' in the Code the Committee discussed whether the Therapeutic Goods Act and the Code of Conduct may conflict in this instance, however members considered that the Code can be more restrictive than any requirement under the legislation."

The ability of the CoC to be "more restrictive" is acceptable however it does not resolve the conflict as the CoC is not uniformly applicable across the therapeutic goods industry. Medicines Australia conceded that the supplier had approval under the TGAC and Section 42DF(1) of the *Therapeutic Goods Act* 1989 for DTC promotion and was not in breach. Which Code is a supplier therefore to follow?

Further Advice Sought from the TGA

Novo Nordisk recently sought clarification from the TGA about the advertising of therapeutic/medical devices to the general public. The TGA's response was in line with our interpretation of the current Therapeutic Goods Advertising Code in that Novo Nordisk was permitted to promote a selected number of our insulin delivery devices to the general public (albeit with appropriate exemption under Section 42DF(1) of the *Therapeutic Goods Act* 1989). Specifically, our understanding is that we are permitted to promote those devices that are distributed independently from the active ingredient (ie. the NovoPen® series and Innovo® device) under the TGAC.

Medicines Australia informed Novo Nordisk that the TGA were consulted recently over this issue. We were advised that the TGA agreed with the proposed amendment to Edition 15 but a written acknowledgment of this was not provided. Novo Nordisk is puzzled as to why the TGA would

agree to a revised guideline that is in conflict with its own TGAC requirements, which may make the amendment ineffective. Furthermore, the advertising group at the TGA did not confirm the existence of any draft amendment to the TGAC to address this issue.

How the Amendment to Section 9.4 Might be "Detrimental to Competition"

Novo Nordisk also sought clarification from Medicines Australia as to how this proposed amendment to the CoC will be applied to other suppliers of insulin delivery devices that do not supply prescription medicines and we are yet to receive a response. One example is provided above in section 1(iv) above (eg. pen device-only supplier). Subcutaneous insulin infusion pumps are also insulin delivery devices that are supplied separately from the medicine (insulin) and are available without a prescription. Suppliers of these devices have also received exemption by the TGA to be promoted directly to the general public as they qualify under the conditions outlined in the Therapeutic Goods Advertising Code.

> Published in the Commonwealth of Australia Gazette No. GN 49, 8 December 2004 (http://www.tga.gov.au/advert/insulinpumps.htm)
>
> *"THERAPEUTIC GOODS ACT 1989/THERAPEUTIC GOODS REGULATIONS*
>
> *I, RITA MACLACHLAN, Director, Office of Devices, Blood and Tissues, Therapeutic Goods Administration and delegate of the Secretary to the Department of Health and Ageing for the purposes of Section 42DF(1) of the Therapeutic Goods Act 1989, give notice that the restricted representation described in paragraph (a) below, has been approved for use in advertisements directed to consumers, for the category of products listed in paragraph (b) provided the conditions identified in paragraph (c) are met:*
>
> *(a) Representations to the effect that use of the goods described in paragraph (b) below: "used in the treatment of diabetes for people diagnosed with this condition";*
> *(b) Powered insulin infusion pumps and insulin pump administration sets; and*
> *(c) (i) The medical devices must first be included in the Australian Register of Therapeutic Goods.*
> *(ii) Advertisements in which the representation is made must comply with the Therapeutic Goods Advertising Code and must advise consumers to seek advice from their medical practitioner.*
> *(iii) Advertisements for the goods in which the representation is made must not refer, either directly or indirectly, to any (Schedule 4) prescription-only medicine.*
>
> *Dated this 26th day of November 2004*
>
> *RITA MACLACHLAN*
> *Delegate of the Secretary to the Department of Health and Ageing"*

Please note that requirement C(iii) above states that the representation must not refer, either directly or indirectly, to any prescription-only medicine. The intention is clearly to prevent the surrogate promotion of a specific medicine but it does not state that the device must be compatible with medicines from more than one company. Novo Nordisk is therefore uncertain as to why the new CoC guidelines for DTC advertising should be applicable to suppliers of prescription medicines but may not be relevant to other device suppliers that responsibly follow the TGAC.

Novo Nordisk argues that this apparent conflict is "detrimental to competition" in general, it provides a potential advantage for individual device suppliers over device & medicine suppliers

due to the respective Codes that they must follow, and potentially non-member companies over member companies based on jurisdiction. Furthermore, selected insulin suppliers have their medicines promoted by default if only a limited number of devices were able to be promoted to the general public as of 01 Jan 2006. These concerns were discussed with Medicines Australia but unfortunately are not resolved with the text proposed in Edition 15.

How the Amendment to Section 9.4 Might be "Detrimental to the Public"

As stated previously, Novo Nordisk is the Australian market leader in insulin delivery and has an established reputation in the development of premium delivery devices. Clinical studies have demonstrated improvements in the quality use of medicines after patients switch to insulin pen devices from vials & syringe:

> *"Because patients were more physically and psychologically comfortable injecting insulin with the Novolin Prefilled or NovoPen 1.5 system than with an insulin syringe, their overall attitude toward insulin therapy improved, as did their confidence about managing their disease. An improved attitude toward insulin therapy might be expected to lead to better acceptance of and compliance with an insulin regimen."* *Graff MR & McClanahan MA. Clinical Therapeutics 1998; 20(3): 486-496.*

This issue is therefore important to us as it relates to our fight to break down the barriers to effective insulin therapy in diabetes management. Novo Nordisk is supported by diabetes health care professionals across Australia in our attempts to demystify insulin delivery for people with diabetes. Novo Nordisk would argue that appropriate DTC promotion of all qualifying insulin delivery devices is important in achieving this shared goal and is important in our fight against the complications of poorly controlled diabetes.

In summary, Novo Nordisk values the opportunity to provide a written submission to the ACCC and is committed to the development of both an effective and equitable Code of Conduct. We fully support the ongoing revisions to the Medicines Australia CoC but look forward to any advice the ACCC can provide on this important issue.

Kind Regards

Dr Shaun O'Mara
Medical Advisor