PART B – ISSUES WITH THE CONSULTATION PROCESS AND PAPER

Summary

In Ego's view the principal deficiencies with the consultation process and paper are that:

- The COAG Principles of Best Practice Regulation have not been taken into account.
- Critical views of an External Reference Group specifically set up to advise the TGA on this consultation were not taken into account.
- Insufficient time has been allowed to prepare a comprehensive industry response with tested alternative proposals.
- The paper contains errors and inconsistencies which resulted in a lack of clarity and which made interpretation difficult.
- The figures include material which is not explained in the text, which do not comply with current labelling requirements, demonstrate a lack of internal consistency within the Consultation paper and imply additional proposals.
- No attempt was made to appropriately segregate the evidence of risk in relation to prescription and non-prescription medicines.
- No evidence was provided that the proposed reforms will achieve the stated objectives of the review.
- The Consultation paper anticipates that all the proposed changes can be incorporated into a single Therapeutic Goods Order.
- The poor quality of the Consultation paper has resulted in a significant waste of industry resources in having to understand and address the scope and nature of the proposed changes .
- The proposed changes involve both increased font sizes and increased levels of content. The inevitable consequence of this will be an increase in the physical dimensions of the product packaging. The ramifications of this will be far-reaching and extremely costly.

Each of these deficiencies is discussed in more detail on the following pages.

A more complete discussion of our concerns is presented in ASMI's letter to Dr John Skerritt (of 12 July) which has been included in Appendix 1.

Ego Pharmaceuticals Pty Ltd
21-31 Malcolm Road, Braeside, 3195, Australia
Tel: +61 3 9587 1088 Fax: +61 3 9580 7647 ask@egopharm.com
ABN 86 005 142 361

COAG principles

COAG has agreed that all governments will ensure that regulatory processes in their jurisdiction are consistent with the following principles:

> *1. Establishing a case for action before addressing a problem;*
> *2. A range of feasible policy options must be considered, including self-regulatory, co-regulatory and non-regulatory approaches, and their benefits and costs assessed;*
> *3. Adopting the option that generates the greatest net benefit for the community;*
> *4. In accordance with the Competition Principles Agreement, legislation should not restrict competition unless it can be demonstrated that:-*
>
> *(a) The benefits of the restrictions to the community as a whole outweigh the costs, and*
>
> *(b) The objectives of the regulation can only be achieved by restricting competition;*
>
> *5. Providing effective guidance to relevant regulators and regulated parties in order to ensure that the policy intent and expected compliance requirements of the regulation are clear;*
> *6. Ensuring that regulation remains relevant and effective over time;*
> *7. Consulting effectively with affected key stakeholders at all stages of the regulatory cycle; and*
> *8. Government action should be effective and proportional to the issue being addressed.*

Ego suggests that the TGA has not properly complied with these principles, because:

- A case for action has not been established in relation to the labelling of non-prescription medicines (principle 1).
- A range of feasible policy options have not been considered (importantly, there is no evidence that the TGA has considered self-regulatory, co-regulatory or non-regulatory approaches) (principle 2).
- There has been no attempt to demonstrate that the proposed changes generate the greatest net benefit for the community (principle 3).
- The impact on the brands of non-prescription medicines is likely to be profound (and competition thereby restricted). However, the TGA has not demonstrated that either; the benefits of the restrictions to the community as a whole outweigh the costs, or; that the objectives of the regulation can only be achieved by restricting competition (principle 4).
- The TGA has not consulted effectively with affected key stakeholders at all stages of the regulatory cycle. Notably the TGA has not provided sufficient time to prepare a comprehensive industry submission (see below). Further the TGA has ignored key recommendations of the External Reference Group established in advance of the Consultation Paper being published (see below) (principle 7).
- The proposed changes are not proportional to the issues being addressed. Firstly, the risks associated with non-prescription labels and packaging have not been properly articulated. Secondly, the proposed changes are to be applied across the entire spectrum of medicines (irrespective of risk)(principle 8).

Ego Pharmaceuticals Pty Ltd
21-31 Malcolm Road, Braeside, 3195, Australia
Tel: +61 3 9587 1088 Fax: +61 3 9580 7647 ask@egopharm.com
ABN 86 005 142 361

The recommendations of the External Reference Group have been ignored

On 26 October 2011, representatives from industry, consumer and healthcare professional groups met to discuss possible solutions to the ten key labelling issues identified from previous consultations regarding labelling. These issues included:

- space for dispensing labels,
- look alike sound alike names and look alike packaging,
- active ingredient prominence,
- small container labelling requirements,
- pack inserts,
- umbrella branding / name extension,
- standardised label design,
- blister pack labelling,
- child resistant closures, and
- tamper evident packaging.

The following extracts are taken from the minutes of that meeting [emphasis added]:

> *"Throughout the discussion there were several recurring suggestions for reforming medicines labelling, including consideration of separate requirements for different classes of medicines; the use of a review panel for assessing names and labels prior to market authorisation; and the use of emerging technologies for providing access to information. It was also recognised that there was considerable overlap of the issues and the potential solutions, and it was proposed that a whole of label approach may provide a better consumer safety outcome than focussing on the individual issues in isolation. There was also strong support for harmonising with existing requirements in other jurisdictions where possible."*
>
> *"The need to provide evidence to support the need for reform was also discussed throughout the day. In order to develop this evidence base, the TGA will work with several members of the external reference group to support the need for change. This evidence will be included in the discussion paper which will be released for public consultation."*
>
> *"The importance of transparency and consistency in decision making was also recognised for all stakeholder groups. It is expected that this will be reflected in any new labelling requirements and associated guidelines."*

It is disappointing therefore that these pertinent assertions have been ignored by:

- Co-mingling prescription and non-prescription issues and solutions.
- Proposing the same changes to all the different classes of medicines.
- Proposing uniquely Australian requirements which fly in the face of harmonisation.

Ego Pharmaceuticals Pty Ltd
21-31 Malcolm Road, Braeside, 3195, Australia
Tel: +61 3 9587 1088 Fax: +61 3 9580 7647 ask@egopharm.com
ABN 86 005 142 361

Insufficient time has been allowed

In our view, the TGA has not allowed sufficient time to prepare a comprehensive industry response to reforms on the scale and of the magnitude put forward in the consultation paper.

As indicated above, we requested an extension for the following reasons:

- The magnitude/scale of changes
- Insufficient time had been allowed to assess the changes, understand the implications of the proposed changes, develop and prepare alternatives, test those alternatives and synthesise all the issues into a comprehensive industry submission.
- The proposed changes were not clear and we suggested that until clarification was made that it was not possible to properly assess the proposed changes and respond to them. On this point, we believe that the consultation paper contains sufficient errors and inconsistencies so as to compromise the consultation process itself.
- In order to develop a full and considered response to the consultation, we needed to develop alternative proposals, test those proposals and assess the impacts of the proposed changes and the alternatives. We could only do that if the proposals were clear.
- In addition to the changes to the product packaging, we would also need to consider the flow-on effects to secondary packaging and the whole supply chain.
- We would need to estimate the cost implications for developing new packs that were unique to Australia.
- In order to achieve this, we needed an extension of time at least until the end of November to respond to the consultation in full.
- Within the current timeframe, we would only be able to provide a preliminary response to the proposed changes (as we understood them); we would not be able to put forward developed or tested alternatives.

Ego Pharmaceuticals Pty Ltd
21-31 Malcolm Road, Braeside, 3195, Australia
Tel: +61 3 9587 1088 Fax: +61 3 9580 7647 ask@egopharm.com
ABN 86 005 142 361

Errors and inconsistencies with the information provided

Ego is concerned that the proposed changes in the consultation paper are not sufficiently clear because the paper itself contains the following errors and inconsistencies with regard to the information provided:

- The consultation paper does not indicate that the labelling requirements for prescription and non-prescription products are currently different, nor does it explain the reasons for the different requirements.
- The consultation paper fails to clearly articulate how (or if) the proposed changes will apply differently to Prescription medicines, OTC medicines and Complementary medicines. This is inconsistent with the TGA's risk-based approach.
- Section 3 includes the erroneous amalgamation of four separate issues (look-alike sound-alike products, different strengths within a prescription medicine brand, umbrella branding and indication specific branding) into a single topic applicable to both prescription and non-prescription products. These four topics ought to be addressed separately because they each represent different sets of risks and they each have varying relevance for prescription and non-prescription products.
- Confusingly, the consultation paper introduces a new term "Look-alike medicine branding" in place of the internationally recognised term "umbrella branding".
- The consultation paper does not define the term "look-alike/sound-alike" which is generally linked to confusion between prescription medicine brand names.
- The term "complementary medicines" is defined differently on pages 6 and 12 and in any event the consultation paper does not properly indicate that complementary medicines can be prescription or non-prescription (as well as being listed or registered).

<u>These errors make it difficult to assess the basis and/or the merits of the proposed changes.</u>

Ego Pharmaceuticals Pty Ltd
21-31 Malcolm Road, Braeside, 3195, Australia
Tel: +61 3 9587 1088 Fax: +61 3 9580 7647 ask@egopharm.com
ABN 86 005 142 361

Errors and inconsistencies in the figures

The figures presented throughout the Consultation Paper contain numerous faults which impair the consultation process. These can be summarised as follows:

- Material is included in the figures which are not explained in the text. Because these inclusions are not discussed, respondents will be unable to assess and comment on the reasoning for their inclusion. Similarly, respondents will be unable to develop and propose suitable alternatives. Also, respondents are unable to determine whether or not the apparent changes are intentional or an oversight. This absence of commentary makes it difficult to assess the basis and/or the merits of the proposed changes as well as the actual scope of the consultation.
- Figures are included which do not comply with current labelling requirements. In reviewing the label examples provided, Ego notes a number of examples where the current requirements have not been complied with. This lack of compliance means that the examples do not accurately reflect the impact of the proposed changes. Furthermore, respondents are unable to tell whether the examples reflect further changes not explained in the text.
- There is a lack of internal consistency within the consultation document. In reviewing the label examples provided, Ego notes a number of examples where there are inconsistencies between the figures themselves and between the figures and the written content of the consultation paper. This lack of consistency makes it difficult to assess the basis and/or the merits of the proposed changes as well as the actual scope of the consultation.

A more complete discussion of our concerns with the figures (listing the errors and inconsistencies) is presented in ASMI's letter to Dr John Skerritt (of 12 July) which has been included in Appendix 1.

Ego further notes that figure 10 (which purports to show compliance with the proposed changes) shows a perforation which will separate every piece of required information into two incomplete parts. This figure cannot represent the proposed changes.

Ego notes that the launch of the consultation paper was delayed so as to incorporate these figures. It is therefore disappointing that instead of aiding the consultation the figures confuse it.

Ego Pharmaceuticals Pty Ltd
21-31 Malcolm Road, Braeside, 3195, Australia
Tel: +61 3 9587 1088 Fax: +61 3 9580 7647 ask@egopharm.com
ABN 86 005 142 361

Insufficient Evidence has been provided

No attempt was made to appropriately segregate the evidence of risk in relation to prescription and non-prescription medicines.

In relation to the TGA's stated "risk-based approach to regulation", the TGA states that:

> *"One of the roles of the TGA is to regulate therapeutic products based on an assessment of the evidence of the risks compared to the benefits of the therapeutic products. The TGA does this by applying scientific and clinical expertise."*[1]

Despite this, the Consultation paper proposes uniform solutions across medicines categories. We do not support such a blanket approach.

Furthermore, no evidence was provided that the proposed reforms will achieve the stated objectives of the review.

Ego is unaware of any evidence suggesting that the current labelling requirements for non-prescription products are inadequate or represent a risk to consumers.

Anticipation of a single Therapeutic Goods Order

Ego notes that the Consultation Paper anticipates that the proposed changes will be encompassed in a Therapeutic Goods Order. Ego suggests that the issues raised in the consultation paper and the proposed changes are too complex to be adequately addressed through a Therapeutic Goods Order alone. In fact, Ego suggests that a number of guidelines will be necessary to complement any Therapeutic Goods Order.

Resource implications from a poor quality Consultation paper

The errors and inconsistencies in the Consultation paper, coupled with the complex and wide-ranging implications of the proposed changes has resulted in a significant amount of time and money being spent by Ego in preparing this response.

See Appendix 2 for an estimate of the amount of time and money spent to date on this response by Ego.

Ego suggests that a lot of this time and money was spent as a direct result of the issues surrounding the quality of the consultation paper and the consultation process. Much of this cost could have been avoided.

[1] http://www.tga.gov.au/about/tga-regulatory-framework.htm

Pack size implications

The proposed changes involve both increased font sizes and increased levels of content. The inevitable consequence of this will be an increase in the physical dimensions of the product packaging. The ramifications of this will be far-reaching and extremely costly.

In our response we have made no attempt to address this complication in detail or to quantify the significant costs associated with any such change. Indeed, any attempt to address this issue in the absence of finalised proposals would be premature.

Having said that, we wish to point out that there will be numerous and significant flow-on implications should the physical dimensions of the product packaging increase to accommodate the reforms, some of these implications include:

- Increased costs associated with capital equipment and facilities.
- Increased costs of packaging (both primary and secondary).
- For imported goods, increased costs of unique Australian packaging and overhead recovery for down time and line changeovers (which could impact on the viability of Australian specific production).
- Decreased freight efficiencies.
- Storage space implications at the manufacturer, wholesaler and retailer levels.
- Shelf-space implications at retail level (with impacts on planograms and line fees to stock product).
- The extra packaging materials will result in increased wastage and possible incompatibilities with the Australian Packaging Covenant.

<u>The financial impact of changes to the physical dimensions of the packaging should not be under-estimated.</u>

Ego Pharmaceuticals Pty Ltd
21-31 Malcolm Road, Braeside, 3195, Australia
Tel: +61 3 9587 1088 Fax: +61 3 9580 7647 ask@egopharm.com
ABN 86 005 142 361

APPENDIX 1 - Letter to Dr John Skerritt

Australian Self-Medication Industry Inc
Suite 2202, Level 22, 141 Walker Street,
North Sydney NSW 2060
PO Box 764, North Sydney NSW 2059
Ph +61 2 9922 5111 Fax +61 2 9959 3693
Email: info@asmi.com.au www.asmi.com.au
ABN 55 082 798 952

12 July 2012

Dr John Skerritt
National Manager
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

Email: John.Skerritt@tga.gov.au

Re: TGA Medicine Labelling and Packaging Review

Dear Dr Skerritt,

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care products in Australia. ASMI also represents related businesses including advertising, public relations, legal, statistical and regulatory consultancy companies and individuals.

Thank you for agreeing to meet with ASMI representatives on Friday 13 July to discuss the TGA's Labelling and Packaging Review.

In advance of that meeting we would like to outline for you our concerns and our reasons for seeking an extension to the closing date for submissions.

Introduction

As you know the TGA's Labelling and Packaging Review will close on 24 August 2012.

ASMI is meeting with you to discuss an extension to this deadline for two reasons:

- Even if the proposed changes were clear, 3 months does not allow sufficient time to assess the changes, develop and prepare alternatives, test those alternatives and synthesise all the issues into a comprehensive industry submission.

- However, the proposed changes are not clear and we suggest that until clarification is made then it is not possible to properly assess the proposed changes and respond to them. On this point, we believe that the consultation paper contains sufficient errors and inconsistencies so as to compromise the consultation process itself.

These two reasons are expanded upon below.

We would also like to note that all eight topics in the consultation paper are relevant to non-prescription products and the proposed changes will have a significant impact on both OTC and Complementary Medicines (in terms of brands and products).

1. Insufficient time allowed

The consultation paper was released on 24 May 2012. At that time ASMI notified members of its release and commenced reviewing the paper. We have held preliminary meetings with our subcommittee and working group representatives and members have agreed on the main issues and a draft timeline for the response.

Members have also agreed to develop artwork incorporating the TGA proposals (as we understand them) across a range of OTC and complementary products and pack sizes.

We have scheduled a 2 day workshop for our members (on 25 and 26 July) to examine the issues in depth and to develop alternate proposals.

We have continued to examine the consultation paper in detail and are preparing an issues paper for workshop participants.

However, in order to develop a full and considered response to the consultation, we need to understand the implications of the proposed changes, develop alternative proposals, test those proposals and assess the impacts of the proposed changes and the alternatives. We can only do this if the proposals are clear.

In addition to the changes to the product packaging, we will also need to consider the flow-on effects to secondary packaging and the whole supply chain. We will also need to estimate the cost implications for developing new packs that are unique to Australia.

Having said that, we provide the following broad outline of the time required:

Action	Est. Timing	Est. Date of completion
Develop revised artwork to comply with the proposals contained in the consultation as we understand them.	6 weeks	To be available for the ASMI workshop on 25 and 26 July.
Review and identify alternate approaches to address the perceived intent of the labelling proposals.	2 weeks	9 August
Develop alternate artwork.	6 weeks	20 September
Test the current, proposed and alternate labels with consumers.	8 weeks	15 November
Concurrently prepare case studies. Assess the cost implications to capital equipment, packaging, secondary packaging, shipping, storage, shelf space and line fees. Assess the environmental impact.	8 Weeks	15 November
Prepare of a comprehensive response.	4 weeks	13 December

Ego Pharmaceuticals Pty Ltd
21-31 Malcolm Road, Braeside, 3195, Australia
Tel: +61 3 9587 1088 Fax: +61 3 9580 7647 ask@egopharm.com
ABN 86 005 142 361

In order to achieve the above, we therefore request an extension of time at least until the end of November to respond to the consultation in full. Within the current timeframe, we would only be able to provide a preliminary response to the proposed changes (as we understand them); we would not be able to put forward developed or tested alternatives.

2. Issues with the consultation document itself

As mentioned above, we are concerned that the proposed changes in the consultation paper are not sufficiently clear because the paper itself contains errors and inconsistencies. We suggest that if the consultation paper is unclear to industry representatives then it must be even less clear to consumers.

This is of particular concern because the consultation paper states that: "care has been taken to develop a paper that can be easily understood by a consumer audience".

The consultation paper indicates that responses should include: "whether or not you support the proposed changes" and "an assessment of how the proposed change will impact on you or your business". We would argue that no such opinion can be formed and no such assessment made while the precise nature of the proposed changes remains unclear.

We would like to draw your attention to the following errors and inconsistencies in the consultation paper.

2.1 Co-mingling of prescription and non-prescription requirements, issues, proposals

The consultation paper does not indicate that the labelling requirements for prescription and non-prescription products are currently different, nor does it explain the reasons for the different requirements. This has proven confusing for industry.

Further, the consultation paper fails to clearly articulate how (or if) the proposed changes will apply differently to Prescription medicines, OTC medicines and Complementary medicines. This is inconsistent with the TGA's risk-based approach and seems to suggest, for example that consumers will have the same difficulties with a sunscreen label as they would with the label of a prescription product.

Section 3 includes the erroneous amalgamation of four separate issues (look-alike sound-alike products, different strengths within a prescription medicine brand, umbrella branding and indication specific branding) into a single topic applicable to both prescription and non-prescription products.

These four topics need to be addressed separately because they each represent different sets of risks and they each have varying relevance for prescription and non-prescription products.

Ego Pharmaceuticals Pty Ltd
21-31 Malcolm Road, Braeside, 3195, Australia
Tel: +61 3 9587 1088 Fax: +61 3 9580 7647 ask@egopharm.com
ABN 86 005 142 361

Confusingly, the consultation paper introduces a new term "Look-alike medicine branding" in place of the internationally recognised term "umbrella branding".

The consultation paper does not define the term "look-alike/sound-alike" which is generally linked to confusion between prescription medicine brand names.

ASMI notes that the term "complementary medicines" is defined differently on pages 6 and 12 and in any event the consultation paper does not properly indicate that complementary medicines can be prescription or non-prescription (as well as being listed or registered).

As a member of the External Reference Group, ASMI saw the previous draft (dated October 2011) which more clearly differentiated the prescription and non-prescription issues and proposals. On this point, ASMI notes that the separation of prescription and non-prescription issues has been an integral, long-standing and consistent part of previous regulatory discussions; not just in relation to labelling and not just between the TGA and industry (but between all stakeholders).

This co-mingling makes it difficult to assess the basis and/or the merits of the proposed changes.

2.2 Material included in the figures which is not discussed in the text

In reviewing the text of the consultation paper against the label examples provided, ASMI notes the following items included in the figures but not discussed in the body of the paper:

- The inclusion of the Company Name immediately prior to the Brand Name on all panels in which the Brand Name appears.
- The inclusion of the TGA website URL www.tga.gov.au immediately under the AUST L/R number on the front panel.
- The mandatory inclusion of the Country of Origin immediately under the company address (in figure 2) as well as on the back of the pack under "Storage information".
- The inclusion of CMI style statements on the back of the pack. For example the statement "your doctor may have prescribed TGGeneral for another reason" in figure 2, which is wholly inappropriate for a non-prescription medicine.
- The description of the dose form under "Storage Information".

Because these inclusions are not discussed, respondents will be unable to assess and comment on the reasoning for their inclusion. Similarly, respondents will be unable to develop and propose suitable alternatives.

The absence of commentary makes it difficult to assess the basis and/or the merits of the proposed changes as well as the actual scope of the consultation.

Ego Pharmaceuticals Pty Ltd
21-31 Malcolm Road, Braeside, 3195, Australia
Tel: +61 3 9587 1088 Fax: +61 3 9580 7647 ask@egopharm.com
ABN 86 005 142 361

2.3 Figures which do not comply with current labelling requirements

In reviewing the label examples provided, ASMI notes a number of examples where the current requirements have not been complied with:

- The SUSMP requirements in relation signal headings and their sizes do not appear to have been met, nor has the requirement that nothing else appear on the same line as the signal headings (see for example, figure 3).
- The statement "Do not use if package is broken or damaged" (see for example, figure 2) is not, in fact, an appropriate tamper-evidence statement. ASMI also notes that the label examples otherwise make no provision for statements about child-resistant-packaging or tamper-evident-packaging.
- Figure 7 contains a fictional schedule ("Pharmacy Only Medicine").

The requirements in relation to barcode sizes and locations also do not appear to have been complied with.

This lack of compliance means that the examples do not accurately reflect the impact of the proposed changes.

2.4 Lack of internal consistency within the consultation document

In reviewing the label examples provided, ASMI notes a number of examples where there are inconsistencies between the figures themselves and between the figures and the written content of the consultation paper:

- In relation to the back of the pack, which if any of the following must appear above the active ingredient information; the signal words, the cautionary statements, the product name, the term "Medicine Information Box" (see for example, figure 7 which includes all four)(see for example figure 2 which only includes one).
- In relation to the back of the pack, the heading "when using this product" appears in figures 6 and 8, but not in figures 2 and 7.
- In relation to the back of the pack, a physical description of the product appears under the heading "storage information" in all the figures except figure 7.
- In relation to country of origin, the mandatory inclusion of the Country of Origin immediately under the company address is shown in figures 2, 3 and 8, however this information also appears on the back of the pack under "Storage information" in figure 2 (but in no other figure) and appears above the company name in figures 11 and 12.
- The indications appear on the front of pack in figure 4, but on no other packs.
- Figure 3 is supposed to illustrate the proposal for including a paracetamol warning statement on the label of a non-prescription pack (but is in fact a prescription product/label).
- In accordance with proposal 1.1, the active ingredient must be listed immediately below the brand name. However, figures 4 and 8 do not show this. Also, figures 2, 4 and 11 present the amount of active ingredient differently.

Ego Pharmaceuticals Pty Ltd
21-31 Malcolm Road, Braeside, 3195, Australia
Tel: +61 3 9587 1088 Fax: +61 3 9580 7647 ask@egopharm.com
ABN 86 005 142 361

This lack of consistency makes it difficult to assess the basis and/or the merits of the proposed changes as well as the actual scope of the consultation.

3. Other concerns

We have confined our comments above to our concerns about the consultation document itself. Although we do have significant concerns with the *merits* of some of the proposed changes, we intend to address those issues as part of our formal response to the consultation document.

Having said that, we are concerned that certain of the COAG Principles of Best Practice Regulation have not been applied to this consultation and we are also concerned that the consultation paper does not discuss international harmonisation (particularly since a number of the proposals appear to be uniquely Australian).

4. Summary

ASMI has sought a meeting with you in order to present the above concerns and to discuss an extension to the 24 August deadline. ASMI's concerns can be summarised thus:

- Even if the proposed changes were clear, 3 months does not allow sufficient time to prepare a comprehensive industry submission.
- However, the proposed changes are not clear and so it is not possible to properly assess the proposed changes and respond to them.

In ASMI's view, the errors and inconsistencies in the consultation paper have jeopardised the consultation process itself. We therefore also seek a discussion on how best to remedy the consultation paper and inform affected stakeholders.

Yours faithfully,

Steven Scarff
Regulatory and Scientific Affairs Director

Ego Pharmaceuticals Pty Ltd
21-31 Malcolm Road, Braeside, 3195, Australia
Tel: +61 3 9587 1088 Fax: +61 3 9580 7647 ask@egopharm.com
ABN 86 005 142 361

APPENDIX 2 - AMOUNT OF TIME & MONEY SPENT TO DATE BY EGO (ESTIMATE)

Department	Time Spent (hours)
Regulatory	84
Scientific Affairs	20
Artwork	1
Total time spent	**105**

Additional expenses (ASMI workshop)	Cost ($)
Flights x 2 (for 2 employees)	480
Accommodation x 2 (for 2 employees)	866
Total additional expenses spent	**1346**