Ego Pharmaceuticals response to the Regulation Impact Statement: General requirements for labels for medicines

1. Overview of Concerns

Ego appreciates the TGA’s initiatives to establish an economic model to determine the financial impact of regulation and to assist in scenarios planning to identify transition timeframes to modulate the impact on industry. However we are concerned that the impact of this significant change on industry has been severely discounted in this document.

Some significant outcomes of *TGA Medicine Labelling and Packaging Review Consultation August 2012*, were that

- TGA has no intention of implementing reforms that result in increases in the physical dimensions of packs/cartons
- TGA understands the importance of branding for non-prescription medicines and the reforms are not intended to impact on branding

The *Regulation impact statement - General requirements for labels for medicines* (the RIS document) is therefore written with the fundamental assumption that this Regulation is intended as a change to labelling only. That is, it will not impact branding and it will not require changes to current packaging specifications (dimensions or types) nor therefore require investment in packaging equipment or tooling. However, the consultation draft of the TGO 79 (as proposed) does have significant impact, particularly on registered non-prescription medicine labelling, which if implemented would require changes to packaging specifications and branding across the majority of our products.

Therefore the RIS document as scoped is not reflective of the currently proposed change to regulation.

It is important that the true cost to industry of such an enormous undertaking as TGO79 is acknowledged and an appropriate transition period is therefore allowed. Ego are concerned that the assumptions used to underpin the economic model underestimate and unreasonably discount the costs to the industry and to the registered non-prescription medicine sector in particular. This in
effect trivialises the scale of the investment the industry will make to further fortify the safety of medicines in the Australian regulatory environment.

The costs of the reform as calculated and reported by the RIS document for the whole industry are very minor for Option 3(c.) 4 year transition period - Total costs per year over 10 years for this option are $0.7 million per annum. This compares starkly with the costs Ego is calculating and will need to make budgetary provision for. So why are these assessments of cost so different? Ego’s response will explore the assumptions which underpin the RIS and why such a difference in costing would occur.

The RIS also provides a Regulation Benefit or net saving of the regulation. This is estimated based on the “2.5 per cent of the total costs [$1.2 billion annually] from incorrect medicine use or $30 million per annum, of hospital admission attributed to medication errors.” We express concern should there be any expectation the $30 million of Regulation Benefit will be delivered year on year in Government Budgets or should it be used as post regulation assessment measurement. We understand the difficulty in determining an appropriate measure of benefit. However we’d value some transparency of the thinking behind this measure at this time the thinking is being applied.
Ego believe the cost to the registered non-prescription medicines sector is disproportionate to the risk arising from that sector particularly when considered relative to the likely benefit arising from this medicine sector.

Ego have worked hard within the overly complex constraints of the consultation draft TGO 79, to provide solutions to minimise the impact of the consultation draft TGO 79 to the intended scope i.e. amendment to labelling only.

Ego would therefore like to see amendments to the RIS assumptions and therefore the costs to industry represented in this document before it is used to support this regulatory initiative so that it properly reflects the cost to industry of these significant medicine labelling changes.

We find the modelling presented in the Regulation Impact Statement (RIS) astounding. Changing labels is time consuming and costly to a company and as such Ego Pharmaceuticals (Ego) aims to minimise the changes required to its labels.

Three options have been presented in the RIS, and Ego offers the following comments on each option.
2. Option 1:

There has been no demonstrated issue with Listed Medicines or Sunscreens.

There has been no issue demonstrated with the vast majority of Registered OTC medicines, in particular topical OTC medicines, such as antifungals, hand sanitisers and hydrocortisone creams.

While labelling changes may be justified for prescription products, to impose the same requirements on all medicines will result in many medications being discontinued in the Australian market, consumer confusion and a loss of brand distinction in the market.

Option 1 is preferred for all non-prescription medicines. The status quo has not been shown to be a risk for consumer for non-prescription medicines, in particular topical OTC medicines.

3. Option 2:

Ego believes it is unfair to imply that the majority of the industry would not comply with voluntary guidance. The majority of the industry is large companies that have significant interest in compliance. Option 2 would allow the majority of packs that are used in multiple countries to be maintained. If Australia is required to have unique requirements, which Option 3 would impose, this is likely to result in many products being discontinued in this market due to the non-viability of having a unique pack for such a small market.

It is offensive to state that there is no expectation of compliance if the guidelines were voluntary. The vast majority of the industry is compliant with current guidelines.

It is also unreasonable to expect that industry would start to adopt guidelines that are in consultation. If industry began adoption of such guidelines prior to finalisation, then work may have to be done and redone, with variations needed each time.

All the labels produced and updated by Ego are compliant with current regulations and guidelines.

4. Option 3:

Option 3 represents an enormous cost to Ego.
4.1 Size of the Change

Ego question if the size of the change has been adequately represented. We particularly note the following two sets of assumptions on page 22 of 28 of the RIS Document:

- “there are a total of 15,800 medicines that would require label changes. Of the 32,500 medicines included in the ARTG, 14,080 have a zero dollar turnover, indicating that they are not currently being sold in Australia. A further 2,660 medicines are for export only and would not be subject to compulsory label changes.”

- “there are 8690 products that are either a single product or the first product in a range of products with the same brand and active ingredient but differing in strength and 7110 products that are second and subsequent strengths.”

The equations here to identify the size of the change are:

**Number of ARTG entries which will be required to change labelling as a result of the Order**

| Total no. medicines included on ARTG (32,500) | no. not being sold (14,080) | no. export only (2,660) | total no. medicines requiring label change (15,760) or 15,800 |

These numbers are very consistent with the numbers provided in the LVT Scheme consultation.

| Total no. medicines included on ARTG (30,460) | no. LVT exemptions (14,078) | = total no. medicines included on ARTG (15,968) |

**Second and subsequent strengths of ARTG entries**

| Of the Total no. medicine entries requiring label changes (15,800) - no. either single or first product under a brand with same active but different strength (i.e separate and distinct entry on ARTG) | second & subsequent strength |


This second and subsequent strength describes products that are a separate and distinct entry on the ARTG. A non-prescription medicine example might be a Children’s single analgesic liquid product in two concentrations, under the same brand. The single strength product labelled suitable for dosing younger children, the double strength product labelled suitable to reduce the volume for dosing older children. However unlike an a prescription medicine for example an injection with a range of different strengths, where the only difference on the label will be the strength, for the non-prescription medicine the labelling across the two strengths will differ markedly.

However, these assumptions do not adequately represent the complexity of the number of labels that need to change to comply with the TGO 79.

The majority of registered non-prescription ARTG entries (and to a lesser extent listed entries) will have more than one stock keeping unit (sku) or pack size (e.g. 1 ARTG entry for Pinetarsol Solution 15ml, 100ml, 200ml & 500ml, or 1 ARTG entry for Aqium Gel 70ml, 375ml & 1L). And while this scenario might sound like the prescription medicine style ‘second and subsequent strength’, where it is only the number of the size of the pack that will differ on the label, this is often not the case.

**E.g. 1.** Pinetarsol Solution 15ml, 100ml, 200ml & 500ml - While the labels may be similar in style, the different sizes and bottle shapes means the text layout must be adapted for each one individually. In total for the one ARTG entry 4 very different labels are needed.

**E.g. 2.** Aqium Gel 70ml, 375ml & 1L - All three pack sizes will have a unique Label artwork, back and front, due to the different pack dimensions and shape. While similar in the design, the label artwork layouts will differ. Due to these packs having front and back labels, the 1 ARTG entry represents 6 different labels.

Additionally many of those pack sizes will have more than one artwork which requires change e.g. for

- Semi-solid creams will have a tube and a carton for each pack size.
- Liquid products can have a bottle label (or a printed or labelled tube) and carton each.

We would therefore expect a multiplier effect to the costs to implement the multiple pack sizes for each entry and the number of pieces of packaging artwork per pack size.
The LVT Scheme Consultation identified a breakdown of number of ARTG entries across the medicine sectors as follows:

<table>
<thead>
<tr>
<th>Type of Therapeutic Good</th>
<th>Number of Units</th>
<th>Annual Charges</th>
<th>LVT Exemptions</th>
<th>Net Annual Charges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescription Medicine – Biologics</td>
<td>1,011</td>
<td></td>
<td>555</td>
<td>456</td>
</tr>
<tr>
<td>Prescription Medicine – Non-Biologics</td>
<td>12,413</td>
<td></td>
<td>7,713</td>
<td>4,700</td>
</tr>
<tr>
<td>Non Prescription (OTC) Medicines</td>
<td>3,506</td>
<td></td>
<td>1,269</td>
<td>2,237</td>
</tr>
<tr>
<td>Listed (Complementary) Medicines</td>
<td>13,116</td>
<td></td>
<td>4,541</td>
<td>8,575</td>
</tr>
</tbody>
</table>

We would estimate that it would be appropriate for Registered OTC Medicines to include a multiplier for number of skus per ARTG entry for:

- Registered non-prescription (OTC) medicines of at least x 2.5.
- Listed complementary medicines of approximately x 1.2.

We’d then estimate a further multiplier of number of pieces of packaging that need to change for Registered non-prescription (OTC) medicines of approximately x 1.5.
4.2 Magnitude of the Change

The RIS delineates all the changes necessary for Option 3 as ‘medium’ or ‘minor’ label changes. We note that for Option 1. – ‘no change’ or just the changes necessary for business as usual those changes too are costed as ‘medium’ for 1st of a product range and ‘minor’ for a second and subsequent product in a range. However for option 1 we need to be clear that these changes are interpreted from the existing TGO 69 onto a label already compliant with TGO 69 and the change is to one product or range of products often with no mandated timeframe for implementation.

Under Option 3 the Ego will be interpreting a completely rewritten Labelling Order, with new definition of terminology and new clauses of requirement. For registered non-prescription medicines the requirements are significantly different. The new prominence of Active will need to be achieved within the Brand and product name design elements with need to reconsider the layout of the front of pack and the MIP will require a complete text re-layout. Ego believe this scale of labelling change is major i.e., complete re-layout of all information in different format, resizing/repositioning of logos/TMs. This will require several attempts at briefing the graphic artist to achieve compliance and optimise the product appearance within the company’s internal artwork approval processes and may require further change during application and evaluation of the variation to the ARTG entry as the sponsor understands how the evaluators interpret the new order.

We understand that sponsors who assisted by providing data to the model provided costs for label change and production costs which have been averaged as follows:

<table>
<thead>
<tr>
<th>Annual Charges</th>
<th>LVT Exemptions</th>
<th>ARTG Entries</th>
<th>Label Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>15,968</td>
<td>23,835</td>
<td></td>
</tr>
</tbody>
</table>
• ‘medium’ level label change, including a number of changes to existing text and adding new text requiring the logo to be moved around (e.g. artwork, redesign) = $1937 per product
• costs for a minor label change to a second or subsequent product in a product range (e.g. artwork, redesign) = $1280 per product
• Production costs for a medium label change (described above) for a single product (e.g. new plate(s)) = $1290
• Production costs for a minor label change to a single product (e.g. new plate(s)) = $900

While medium and minor label changes and production costs are appropriate for Option 1 (on page 17 of 28), we advise that major label changes and production costs for first products in a range and medium for second and subsequent changes should have been costed for Option 3 a. b. and c. for all registered non-prescription medicines label changes (rather than ARTG entries) (on page 22 of 28).

4.3 The Costs to Manage Achieving Compliance within the Transition Time

Option 3 assumes no additional company resource time/cost for:
• Managing this change of all product labels to be compliant for supply ex warehouse within the transition time and to minimise write-off of product and existing printed packaging.
• Incremental increase to briefing and review of label artwork potentially requiring several amendments to achieve all requirements satisfactorily.

The assumption (on page 22 of 28) that “it is estimated that more than half of medicine labels for products marketed in Australia are changed every three years.” seems to assume that therefore no additional time would be required for this extent of change.

However:
• the new regulation represents a ‘hard’ change where all stock must change and be compliant by a set time, not a ‘soft’ change for a couple of skus at a time as is the case for ‘business as usual’ changes, where old stock can be run out and new stock run in. It therefore requires careful cross-functional project management to achieve compliance and minimise stock write-off.
• the time differential to brief and review a very minor wording change to that for a complete interpretation of new requirements in lay out is significant. The likelihood of achieving a satisfactorily outcome in the first brief is also less certain for the latter.

We also note and question why the model does not include assumptions for Option 3 to account for:
1. Write-off costs, both of printed packaging materials and current product still on hand at the end of the transition period? Even with carefully planning of the project, in every sponsor company there will be a level of write-off.

2. Write-off of current promotional materials with pack-shots and preparation and provision of new, a necessary regulatory compliance task.

4.4 Discounting the costs of Regulatory Change based on inclusion of Business change

Ego note and question the appropriateness of the assumptions for Category 2, 3, & 4 changes on page 23 of 28 where - “it is assumed planned changes for business reasons are brought forward to avoid having to pay twice for label changes (once for the regulatory changes, once for the business need).” And the follow-on assumption in Option 3a that only 50% of the costs are attributable to business needs and 50% to the required regulatory changes for category 2, 3 & 4 labels (page 23 of 28) and similar cost discounting assumptions of 3b and 3c.

Typical business reasons for changing labels are; a company merger/acquisition, a global brand redesign, a change of sponsor address and contact details, a change of country of origin, but may also be in response to a substance switch, or a to safety signal or RASML (MASS) update. However some of these cannot be foreseen at the commencement of planning such a big change, others cannot be ‘brought forward’ forward or ‘put back’ to coincide with the new Labelling Order in Australia. Therefore while there will be some serendipitous timings for some brands/companies, the reality is that many labels will need to change twice or more during the transition period.

E.g. We are currently implementing changes to ensure compliance with the Medicines Advisory Statement Specification 2014. We cannot afford to await the new Labelling Order being published to combine the necessary changes and risk not achieving MASS 2014 compliance within the 18 month transition period.

Additionally the high frequency with which business makes changes to labels appears based on the assumption identified as a baseline under Option 1, i.e. 30% of all applications to vary and ARTG entry are variations to labelling. Ego question this assumption after comparing the numbers of ‘label’ applications for each type of medicine when compared to the number of ARTG entry numbers for each type of medicine.
When the number of variations presented is considered relative to the medicine classification and proportional to the number of ARTG entries for that type it becomes clear that:

(a) The vast majority of labelling variations relate to prescription medicines, which would be an unexpected outcome. While attributed to labelling they are instead likely to be variations to Product Information, which is outside the scope of TGO 79. This is significantly distorting the total picture of the frequency with which variations are made to labels across all medicine types.

(b) The number of variations to registered non-prescription medicine labels is low.

(c) The number of labelling variations made to listed medicine labels is very low.

The assumption that other than TGO 79 regulatory change all the other determinants for varying a label are all due to business needs is also questioned. Many of those reasons are due to other regulatory changes. The notion of discounting the costs of the TGO 79 regulation 50% with business when the second determinant of change is another TGA regulatory change is ‘quaint’.

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1 http://www.tga.gov.au/list-evaluated-registered-complementary-medicines
Ego suggests the level of discounting of the cost of the reform is unduly elevated and needs to be fairly addressed.

### 4.5 Opportunity Costs

We understand that a standard opportunity cost factor is determined by the Office of Best Practice Regulation and at the time of preparing this RIS document that standard factor was 6%.

As stated above this is a significant project to manage to make the changes to every label on every of every pack size of every ARTG entry, make the variations to those labels and manage the introduction of the new labels into the supply chain, minimising the write-off exposures to the company.

We suggest that the size of this project will be resource intensive both to the Regulatory and Supply functions within a business and will have significant opportunity cost implications. To meet business growth objectives and achieve labelling compliance, many companies will need to employ supply and/or regulatory contractors to manage the labelling reform. There is no reference for such costs other than the standard OBPR allowance and the following assumption:

> “it takes 20 hours to prepare an application for variation for the first product strength on the ARTG. This time would include updating procedures, policies and the time taken to assemble the necessary information and fill in the form to apply to vary the application. Wage rates for the preparation of the application are $42 per hour.”

### 4.6 Attribution of Costs over 10 years (page 23 of 28)

Although not stated, the RIS document is written around the assumption that the introduction of TGO 79 represents an amendment labelling only. That is, it will not require change to packaging sizes and types and will therefore have no requirement for investment in packaging equipment or tooling. All of the costs to achieve compliance will therefore be incurred by industry over the transition period. After the transition is completed the TGO 79 will be the Standard for Labelling and it will be part of business as usual.

Ego therefore questions why the cost of the Regulation is attributed over a ten year period. Unsure of the rationale for the ten year period, e.g. net present value, amortising the value of capital expenditure over the cost of the product and therefore enquired. We understand the ten year period is the average life expectancy of the Regulation.
As the reality is that all of the cost burden is carried over each scenario’s transition period, the annual cost should be attributed over that transition period. This would more accurately reflect the stresses to industry of the different transition scenarios.

4.7 Frequency of label changes

Ego has 33 Registered OTC medicines, 3 Registered Prescription Medicines, 4 Listed Medicines and 17 Listed Sunscreens. Together these products represent 183 packaging items that will need to be reviewed if TGO 79 comes into force. Ego is not in the habit of changing labels on a regular basis. Table 1 indicates the pattern of label changes over the past 5 years, while table 2 indicates the pattern over the last 3 years. For both tables, it can be seen that other than complying with the new TGA ARGS and AS:NZS 2604:2012, Ego is not in the habit of making regular label changes.

Table 1: Pattern of label changes over the past 5 years

<table>
<thead>
<tr>
<th>Registration Category</th>
<th>Number of products (multiple packs counted as one product)</th>
<th>Number of label updates in the past 5 years</th>
<th>Reason for update</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registered Prescription</td>
<td>3</td>
<td>0</td>
<td>—</td>
</tr>
<tr>
<td>Registered - OTC</td>
<td>33</td>
<td>36 updates to 25 products, 7.2 labels updated / year, 5 products updated / year</td>
<td>2 updates for the removal of minor text/images (self-assessable). 15 updates to overseas registration numbers and/or addressees. 19 updates that involved notifications/variations or new registrations.</td>
</tr>
<tr>
<td>Listed</td>
<td>4</td>
<td>1</td>
<td>Removal of minor logo</td>
</tr>
<tr>
<td>Registration Category</td>
<td>Number of products (multiple packs counted as one product)</td>
<td>Number of label updates in the past 5 years</td>
<td>Reason for update</td>
</tr>
<tr>
<td>-----------------------</td>
<td>----------------------------------------------------------</td>
<td>-------------------------------------------</td>
<td>------------------</td>
</tr>
<tr>
<td>Sunscreens</td>
<td>17</td>
<td>38</td>
<td>Compliance with new TGA ARGS and AS:NZS 2604:2012</td>
</tr>
</tbody>
</table>

Table 2: Pattern of label changes over the past 3 years

<table>
<thead>
<tr>
<th>Registration Category</th>
<th>Number of products (multiple packs counted as one product)</th>
<th>Number of label updates in the past 3 years</th>
<th>Reason for update</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registered Prescription</td>
<td>3</td>
<td>0</td>
<td>—</td>
</tr>
<tr>
<td>Registered - OTC</td>
<td>33</td>
<td>10 updates to 6 products 3.3 labels updated / year, 2 products updated / year</td>
<td>3 updates to overseas registration numbers and/or addressees. 7 updates that involved notifications/variations or new registrations.</td>
</tr>
<tr>
<td>Listed</td>
<td>4</td>
<td>0</td>
<td>—</td>
</tr>
<tr>
<td>Sunscreens</td>
<td>17</td>
<td>38</td>
<td>Compliance with new TGA ARGS and AS:NZS 2604:2012</td>
</tr>
</tbody>
</table>

Ego’s product range of Registered and Listed Medicines comprises 57 products and 183 different label items including bottles, tubes and cartons. All of Ego’s products are topical for which no risk to the consumer under the current labelling has been demonstrated. Inappropriate and incorrect use of topical medicines is not an issue, however under Option 3, every piece will need to be examined and changes made to the majority of them.
The cost to update labels for Ego would not be born under normal business practice as stated, since Ego has a low label update rate outside of compliance with new guidelines and standards. It is vastly incorrect and false to assume that regular changes to medicine labels are part of normal business practice and that half of medicine labels in Ego are changed every three years. As can be seen in Table 2, this is not the case. Excluding the large labelling update to comply with the new TGA ARGs and AS:NZS 2604:2012, Ego has only made 10 updates to 6 of its 40 Prescription / OTC and Listed medicines in the past 3 years.

In fact, in the past 5 years, excluding the large labelling update to comply with the new TGA ARGs and AS:NZS 2604:2012, Ego has made only 37 updates to the 135 labelling items of its Prescription / OTC and Listed medicines. In the coming years the need to meet regulatory requirements will be the primary cause of label updates for Ego Pharmaceuticals and impose a very large cost on the company, see table 3.

The assumptions listed under Option 3 are very different from the reality for Ego Pharmaceuticals. Table 3 indicates the true values experience by Ego Pharmaceuticals.

**Table 3:**

<table>
<thead>
<tr>
<th>Cost Parameter</th>
<th>Cost for Ego Pharmaceuticals</th>
<th>Assumed cost in RIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time taken to prepare an application for variation</td>
<td>50 hours total of all</td>
<td>20 hours</td>
</tr>
<tr>
<td></td>
<td>departments involved</td>
<td></td>
</tr>
<tr>
<td>Cost per hour to prepare the variation</td>
<td>$42</td>
<td>$42</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| % of marketed labels needing to be updated under TGO 79 | 73.8% for Ego               | 48.6% of products on the ARTG  
((15,800 / [32500-14,080-2,600])) |
<p>| Average time in which a label is changed in normal business practice | Greater than 5 years   | 2.9 (rounded to 3) |
| Average pre-production cost for a ‘major’ level label change | There is no substantial difference between a major or medium change for the departments involved: Regulatory Affairs, QA, Marketing, Production, Artwork, Wholesaling, Sales, Administration | - - - |
| Average pre-production cost for a ‘medium’ level label change | Cost is due to time spent: $2,100 per artwork piece | $1,937 |
| Average pre-production cost                         | No change under TGO 79     | $1,280              |</p>
<table>
<thead>
<tr>
<th>Cost Parameter</th>
<th>Cost for Ego Pharmaceuticals</th>
<th>Assumed cost in RIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>for a ‘minor’ level label change</td>
<td>will be ‘minor’</td>
<td>- - -</td>
</tr>
<tr>
<td>Average production cost for a ‘major’ level label change</td>
<td>Production time Plate costs depend on packaging item: Labels vs. Cartons vs. Tubes vs. printed bottle At a minimum, a tube/carton combination will cost $6,000 Since the plates are the major cost, there is no substantial difference between a major or medium change.</td>
<td>$1,290</td>
</tr>
<tr>
<td>Average production cost for a ‘medium’ level label change</td>
<td>No change under TGO 79 will be ‘minor’</td>
<td>$900</td>
</tr>
<tr>
<td>Multiple strengths</td>
<td>This assumption is false as different strengths can have different warnings/cautions and different indications. The same can be said for different pack sizes of the same product It is often not possible to simply cut and paste the changes from one strength to another strength, or from one size to another size.</td>
<td>First change is an ‘average’ or medium change whereas subsequent changes are ‘minor’ changes</td>
</tr>
<tr>
<td>% of products that require changes that are single products or first products</td>
<td>31.1% (57/183)</td>
<td>55% (8690/15800)</td>
</tr>
<tr>
<td>Extra time needed for an application of a product with the same actives plus a different strength</td>
<td>For topical products a different strength is a unique ARTG entry, with a unique label so does not represent a saving of time.</td>
<td>2 hours</td>
</tr>
</tbody>
</table>

For Ego Pharmaceuticals to change the 135 packaging items that would be affected by TGO79, will occupy at least 6750 man hours over various departments, costing $283,500 in labour and $371,600 in direct costs due to printing plates. We have not calculated the cost of disposing of excess packaging or marketing materials but this would be additional for each of the 40 products involved.
We have also not calculated the cost of aligning the new artwork with our international markets and the write off costs that would be associated with this.

Overall complying with TGO 79 as it is drafted represents an enormous consumption of resources and a significant opportunity cost to Ego, an Australian manufacturer. Given the lack of demonstrated risk for topical OTC product, this is an unwarranted imposition.

4.8 Transition period

Given the low rate of ‘normal business’ label updates conducted by Ego Pharmaceuticals, all the transition periods proposed would impose additional regulatory cost. Compliance with the TGO 79 will require Ego Pharmaceuticals to do more than 150 unplanned label updates to tubes, bottles and cartons.

4.8.1 Two year transition / Three year transition

A two or three year transition period would be crippling to Ego’s normal business practises. As an Australian manufacturer we use the Australian label as the basis for our international registration. An Australian label is approved in up to 7 different international markets. To change a label in all these markets once TGA approval is obtained will take between 3 and 8 years depending on the markets involved.

Not only do we need to update our Australian registration for the labels, the international markets would also need their registration updated once approval in Australia has been obtained. If we were forced to implement the new label in Australia before the international approvals had come through, we would need to carry two labels for the one product. This would increase the pressure on our warehouses that would need to hold two different sets of packaging, and two different finished goods for the one product. Production would be delayed when switching from one set of labelling to the second, thus breaking up the run efficacy. It would also require Ego to purchase short print runs of the superseded labelling to maintain supply to the international markets during change over, thus increasing the cost of the packaging and the cost of goods to Ego. When final approvals came through, excess filled product and packaging that could no longer be sold would need to be destroyed, again representing an added cost burden.
4.8.2 Four year transition / Five year transition

A longer transition time, preferably 5 years, would allow for a more co-ordinated plan to be implemented in regards to aligning overseas market with Australian labelling, with approvals being obtained sequentially after the TGA approval. The new approved label could then be implemented at the one time, allowing for superseded packaging to be run out, and minimal wastage created.

Having more than 150 different label items to be reviewed and modified, a 5 year transition period would allow the updates to be done without a significant impact on the normal business of Ego. A shorter transition time would consume the resources of Regulatory Affairs, Quality, Marketing, Artwork and Production and they update and coordinate the changes.

The costs assumed in the RIS are completely out of line with costs experienced by Ego Pharmaceuticals should TGO 79 be implemented as it is written. Ego has a low rate of label artwork change, with very few labels update every year. The estimate that 50% of labels have a change done to them every three years is not true for Ego. The enormity of the change imposed by the TGO 79 as drafted would consume a significant level of resources for Ego over the transition period.

For a company that makes topical OTC products, that are by their nature low risk, to have to comply with the same labelling standards as prescription medicines represents a significant increase in monetary cost and opportunity cost for compliance. It also represents an unsupportable increase in regulatory creep on medicines that are not the cause of the issue attempting to be addressed in the TGO 79.
Ego Pharmaceutical’s response to the draft Therapeutic goods order 79

Ego Pharmaceuticals (Ego) appreciates the opportunity to provide comment on the TGA Medicine Labelling Consultation, consisting of the draft Therapeutic Goods Order (TGO) 79, together with the related guidelines and the Regulation Impact Statement (RIS).

Ego is a wholly Australian owned pharmaceutical company. We manufacture a range of topical medicines; prescription, OTC, sunscreens and registered complementary. Our manufacturing site is based in Melbourne, from where we manufacture all our products for both the domestic and international markets.

1. Labelling of non-prescription medicines – General considerations

Non-prescription medicines are a diverse group of products ranging from very low risk products such as hand sanitising products, confectionery-type throat lozenges, vitamins / minerals, to products such as cough and cold medicines, analgesics, antacids, through to small packs of Schedule 3 medicines such as proton pump inhibitors (PPIs) and antivirals.

Despite these differences, there are some commonalities in labelling of these products. Generally, they are mostly used by consumers in unsupervised situations. It is important, therefore, that the labelling clearly conveys the following information:

- On the front of pack / main label – the medicine’s uses. Consumers shop by “need state” in the grocery or pharmacy front of shop environment. This might be for a pain reliever, cough suppressant, an antacid, a vitamin or mineral, an antifungal cream or an anti-allergy product. For the consumer, this is vital information as they have only minimal knowledge of pharmacology. The front of pack usually also conveys to consumers what the medicine is for, and any specific product attributes that may be important to them, such as “once a day” or the type of dosage form, pack size, etc.

- On the front of pack / main label – the product’s active ingredient(s).

- Other mandatory information on the front of pack / main label – such as signal headings

- On the back of pack – how to use the medicine, warning statements, both mandatory and non-mandatory, additional ingredient information, contact details of the sponsor, and other information – e.g. how to open a package, storage information, etc.
• On the back or side of pack – Barcode. For non-prescription products sold in the grocery environment, truncated barcodes are not allowed and packs must have the full sized barcodes to allow reliable and fast scanning.
• Unvarnished areas for printed / embossed batch number and expiry dates
• Some medicines require additional safety information – e.g. large bottles of hand sanitiser or pressurised containers require the red diamond denoting “flammable” contents, as per Dangerous Goods regulatory requirements.

2. Topicals OTC medicines are low risk medicines
Ego would like to propose that topical OTC medicines be excluded from the labelling requirements due to their low risk nature and minimal risk of adverse event if excess is applied.

For example, the overuse of an antifungal cream is highly unlikely to cause systemic adverse events, neither is the overuse of a pine tar cleanser, an ichthamol ointment or a head lice treatment. In fact, given the consumers propensity to underuse topical medicines, the labelling proposed could increase the consumers concern about their topical medicines, resulting in them using less again and failing to obtain efficacy from the medicine.

As noted later, the small pack sizes used with topical medicines, along with the large font size for the actives makes the products appear frightening, cluttered and in many cases the text no long fits on the packs.

Ego believes that excluding topical OTC medicines from the majority of these labelling requirements, as has been done for sunscreens, will ensure that consumers continue to use the medicines as intended and obtain the desired efficacy without the risk of adverse systemic reactions.

3. Ego’s Position on what the draft TGO 79 needs to achieve
In addition to being focussed on the consumer, the draft TGO 79 should:
• Be easy for industry to adopt and transition to
• Result in no changes to packaging dimensions, or changes to the manufacturing / packaging process,
• Cause minimal or no disruption to business,
• Not require volumes of Section 14 exemptions on a continuing basis and
• It should be easy for industry to understand the requirements and monitor compliance, by both regulatory and non-regulatory personnel.

The draft TGO 79 itself should be precise and not use subjective language or be too interpretive, it should be clear, applicable to the vast majority (if not all) of product and packaging types and it should not disadvantage sponsors currently marketing particular products.

Ego understands that there will probably be a few exceptional cases where exemptions under Section 14 of the Therapeutic Goods Act (S14) are needed. However, S14 exemptions do not provide business certainty and should be rarely required if the draft TGO 79 is truly reasonable, effective and meets the criteria outlined above. S14 exemptions should not be seen as a way of accommodating an ineffective TGO 79.

Ego notes that the existing TGO69 may not have been perfect and is now in need of updating, however labelling exemptions were relatively few and compliance was generally achievable for the vast majority of packaging types.

4. General Comments on the draft TGO 79

Unfortunately, the draft Order as written is over-complicated; inconsistent with the above principles and substantial re-working is needed. There are many unresolved issues in the draft and Ego’s view is that it cannot proceed as is.

In terms of the desired aims of the draft Order, it is likely that these could have been met with some simple updates to the TGO 69 and some further differentiation between product types, i.e. prescription, registered or listed. Instead, the draft Order is difficult to follow, conflates prescription and registered non-prescription medicines by imposing nearly all of the same requirements other than the additional requirement for the Medicine Information Panel (MIP), and does not recognise that there is limited space on many medicine labels.

We believe that the draft Order could have been much easier to follow for all sponsors, both prescription and non-prescription, if it had been structured to include all of the general requirements that apply to all medicine classes in a first section, followed by a section for prescription medicines, a section for registered medicines not in S4 or S8 (which should also include specific exclusions for registered complementary medicines), and a section for listed medicines, followed by the
information on expression of active ingredients and Schedules, etc. Had it been structured in that way, OTC medicine sponsors would not need to work through requirements for injections, biological and dialysis solutions, before getting to important information on the MIP and other sections.

It is clear that there should be more differentiation on the basis of risk – but instead, the draft Order will have an unnecessarily severe impact on some of the lowest risk goods, which happen to also have limited label space – examples are small OTC containers for hand sanitisers and tubes of cream, which will need to change packaging type or dimensions of packaging to accommodate the draft Order.

The combined requirement for an increase to active ingredient font size to the equivalent of 15 points Arial, combined with the formatting requirements of the MIP, has put pressure on the majority of small packs, both tubes and cartons – and particularly affects products that have three or more active ingredients.

The draft Order confusingly attempts to change the way ingredients are expressed on the main label, and consequently there is the possibility that there could be multiple products with the same active ingredient, with different expressions of active ingredient on the label. This would be very confusing for consumers, especially for non-prescription medicines where self-selection occurs, as well as for healthcare professionals. We do not believe that this was the intention of the draft Order, but we suspect that it is instead the result of trying to accommodate the proposed increase in active ingredient prominence together with partial adoption of the UK practice, by allowing some use of common names.

The aim of harmonising labelling requirements cannot be achieved by cherry picking of guidelines or requirements from other jurisdictions. More consideration should be given to how these will work in the Australian regulatory environment, as the new requirements will become an additional feature of the existing regulatory environment that covers registration/listing, scheduling, dangerous goods, etc.

Products that are unable to comply with the TGO will be forced to either change their packaging or format of labelling (e.g. to a concertina / peel-off label) which is a costly proposition, or apply to TGA for a S14 exemption. There are many parts of this draft TGO 79 where the final impact will be either of these two situations. S14 exemptions do not provide certainty as these are designed to be
used for a limited period. We believe that the TGA would also find a large number of S14 exemption applications to be resource intensive and impractical.

Ego has reviewed the draft Order in detail, with our concerns detailed below.

5. Specific Concerns - Active ingredient font size

Ego has concerns about the TGA’s proposals for active ingredient font size.

While Ego understand that the TGA’s objective was to reflect “UK as practiced”, the draft TGO 79 does not reflect UK practice and it imposes a more stringent and onerous approach. Being a legislative instrument, the consequences of not being able to comply are severe.

The draft TGO 79 states [Section 9(7)(a)], for registered medicines: “The name of the active ingredient(s) and the quantity or proportion of active ingredient(s) must be displayed in a text size of not less than the equivalent of 15 point Arial in any sans serif font”. This is applicable to all labels, other than those of small (less than or equal to 25 mL capacity) or very small (less than or equal to 2.5 mL capacity).

Ego has the following concerns regarding the proposed letter height:

- It is a significant increase compared to currently allowed letter height. It represents more than two and a half times the currently allowed 1.5mm letter height (expressed as ascender/descender). The proposed font size of “equivalent to points Arial” is also difficult for compliance measurement within companies, particularly by non-regulatory personnel and those in QA.

- This increased prominence can only be achieved at the expense of other information which consumers, pharmacy assistants and pharmacists require when selecting a non-prescription medicine. Examples are usage information, some claims e.g. “sugar free”, “non-drowsy” or “once a day” provide important information for consumers and it is vital that the increased prominence of actives does not result in this information being removed from product labels.

- Only a proportion of OTC medicines, mainly those in larger packs or with single ingredients would be able to comply. For the remainder, an S14 exemption is required if the draft Order does not change. A large increase in volume of S14 applications is a predictable outcome.
- It is a completely unachievable requirement for many OTC products that are presented in smaller packaging types, smaller bottles, tubes.
- Products that contain more than two active ingredients, even on larger packs, would find it extremely difficult to comply with the proposed font size.
- The proposed font size is not reflective of a risk based approach and applies to all registered products – registered hand sanitisers and bath oils, registered complementary medicines, and low risk OTC medicines.
- The proposed International Harmonisation of Ingredient Names will have a great impact on how the active ingredient names are expressed. Ego notes that the TGA has proposed some changes to how active ingredient naming is to be expressed on labels, by allowing use of the free base/free acid on the main label and the name of the salt on another part of the label. This is discussed further under active ingredient expression. Ego is concerned that this approach to naming of active ingredients has been put forward as a way of allowing for increased prominence; this is not a solution and presents some further concerns around possible consumer confusion.

Ego has reviewed the proposed requirements in relation to active ingredient font size and can offer the following specific comments and examples:

**5.1 Active ingredient prominence diminishing the legibility of other important labelling information**

Consumers rely upon “need state” information when self-selecting a product. For example – chesty cough, dry cough, sugar free, or other product attributes. Some of this information can be very important, and some examples of the impact of the proposed TGO on other, important information for consumers is shown below.
Example 1:
While the active ingredient will need to run over three lines if 15pt font is used, the usage information “Antibacterial hand gel” blends into the background compared to the active ingredient. Not only is this confusing to consumers, it carries significant safety concerns that some people may desire misuse the contents. Other important information such as “No rinse” is invisible.

This is not an example of labelling that would facilitate quality use of medicines.

This is an example of a labelling order that would actually increase risk to consumers.
Example 2:

This example is illustrative of the fact that the uses “relieves inflamed and itchy skin” “pH 6.5”, “soap free cleansing solution”, which are more important to the consumer than the ingredients, take a very subordinate position to the extent that consumers may think it is not even for human use (pine tar).

Note also that the MIP does not fit on this 100 mL container.
Example 3:

We acknowledge poor resolution of this image, but this is an additional example of the product uses being subordinate to the active ingredient, to the point where consumers would be worried and confused about what a medicine with coal tar, phenol and sulphur could possibly be used for.
Example 4:

In this example, the product Resolve Nappy Rash ointment is a combination of miconazole and zinc oxide. As such, it is used for fungally infected nappy rash. This would not be clearly evident when a consumer is self-selecting this product, as most consumers would not know that miconazole is an anti-fungal. They rely on the information on the product indications to guide them towards appropriate use of the product. Indications and uses have almost disappeared from the main label. Again, this is not optimal labelling for a non-prescription medicine.
5.2 Active ingredient prominence interfering with branding or trademarks

The draft TGO 79, as written, will have a profound impact on branding and trademarks unless some clarifications can be made.

The active ingredient font size, as required by section 9(7)(a), when considered together with the requirements for placement in section 9(3)(a) and 9(3)(b) – “The name of the medicine and the name(s) of the active ingredient(s) must be on the main label:

(a) Appear as a cohesive unit by placing the name, and quantity, of each active ingredient together on separate lines of text immediately below the name of the medicine; and

(b) Not be separated by any text or graphics, except where additional information is required by paragraph 11(2)(j) or in relation to medicines contained in a composite pack or a medicine kit”

Section 9(3)(a) states that the name of each active ingredient must be immediately below the name of the medicine. For many medicines, this cannot be achieved without any impact on branding or trademarks.

5.3 Products with multiple active ingredients

Some products, particularly those which are supplied in cartons of reasonably large dimensions, may be able to accommodate a font size of 15 point Arial, especially if they have one or two ingredients.

However, for products containing three active ingredients, this is impossible, as can be seen in the example below where there is insufficient space to fit the ingredients and strengths.
Example 5:

This product is in a standard carton size for holding a 30g tube. The three active ingredients, at a 15 point Arial equivalent font size, overwhelm the main panel, with the indication barely visible.

5.4 Ego Proposals for Active Ingredient font sizes

As clearly seen from the examples shown above, the proposed font size of “the equivalent to 15 points Arial in any sans serif font” is not achievable for many non-prescription medicine product and label types. The font size proposed by the TGA is unsuitable for a many of our products.

Given the variety of product types that cannot be accommodated, Ego would be compelled to apply for S14 exemptions or radically alter the size and design of our packaging.

The draft TGO 79 should be amended so that the active ingredients, as well as the MIP (to be discussed below) may be realistically accommodated on the majority, if not all, labelling. In particular, thought should be given to the following products which by virtue of their sizes/dimensions/capacity are under particular pressure:

- Bottle labels that are either “wrap around”, or separate front of bottle and back of bottle labels for bottles of under 150 to 200 mL capacity. We acknowledge that 200 mL may not
intuitively sound like the label will have difficulty, however some products, e.g. SOOV Burn have separate front and back labels that take up a smaller proportion of the bottle surface area and this is part of their brand equity or heritage.

- Products that have more than two active ingredients. Unlike the UK, Australia will require the strength or concentration of active and disclosure of the salt in most cases.
- Primary packs that accommodate small containers and very small containers, as these will also be proportionately small or very small, i.e. likely to have a proportionately small surface area available on the main label panel.
- Consider that non-prescription medicines require “non-statutory” information, such as product uses and attributes.

**Ego proposes the following:**

- Ego believes that the draft TGO 79 needs to be amended in order to accommodate “intermediate sized non-prescription medicine labels”, which could encompass smaller cartons, labels of bottles – either wrap-around or separate, dispensers, cylinders, tubes, etc.
- Ego proposes that when looking at font size, MIP, and other requirements – labels should be considered on the basis of label surface area or available label space, rather than the capacity of a (bottle/tube) container, which has no applicability to cylinders, tubes, wrappers, cartons, etc. Ego recommends that this may be done by way of looking at the surface area of the main label panel.
- Based on some preliminary testing, Ego recommends that this be defined as “less than or equal to 70 cm\(^2\), i.e. 10 cm x 7 cm. For labels which are “intermediate non-prescription medicine labels” the font size of the active ingredient and strength / concentration should be the equivalent to 8 points Arial in any sans serif font. This can reasonably allow non-statutory information, and possibly up to three active ingredients on the main panel.
- For all other labels, which are larger than “intermediate”, a font size equivalent to 10 point Arial in any sans serif font would be more easily adaptable to most other differently sized or shaped containers.

Since there are various combinations of allowable font sizes depending on pack dimensions, we have summarised our recommendations in this table. For clarity, the Ego suggestions have been highlighted in yellow.

**Section 9(7)(a) should be amended as follows:**

Subject to (8), if the medicine is intended to be, or is, registered goods:
(a) The name of the active ingredients and the quantity or proportion of active ingredient(s) must be displayed in a text size of not less than the equivalent of 10 points Arial in any sans serif font.

(b) For labels with limited space (to be defined, but possibly in terms of main label dimensions of 70 cm² or less for the main panel), the name of the active ingredient and the quantity or proportion of active ingredient(s) must be displayed in a text size of not less than the equivalent of 8 points Arial in any sans serif font.

Section 9(8)(b) requires clarification:

The draft TGO 79 states if “10(20) applies – the names of every active ingredients, together with the quantity or proportion of every active ingredient, need not be displayed on the main label.”

Ego supports this requirement, provided that the font size is equivalent to 6 points Arial in any sans-serif font, either on the main label or on another part of the label (e.g. a side panel).

The draft TGO 79 should introduce:

- A definition of an “intermediate non-prescription label”, suggested to be not more than 70 cm² for the main label – either as a stand-alone main label, the main label panel of a carton, or as the main label section of a wrap-around label.

Summary Table of Ego recommendations

<table>
<thead>
<tr>
<th>Description of pack or label type</th>
<th>Active ingredient / strength font size</th>
<th>MIP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very small container Section (10)(15)</td>
<td>6 point / 4 point</td>
<td>No</td>
</tr>
<tr>
<td>Small container Section (10)(14)</td>
<td>8 point / 6 point</td>
<td>No</td>
</tr>
<tr>
<td>Intermediate label for non-prescription medicines in a carton form or as a stand-alone label or as the main label section of a wrap-around label: Main label panel 70 cm² or less irrespective of whether it is on a tube, bottle label, dispenser as these will likely be below 70 cm²</td>
<td>8 point / 8 point</td>
<td>Truncated or abbreviated MIP allowed - removal of duplicated information, rationalisation of sub-headings; grouping of information under sub-headings required; minor change to order of information if this achieves a better fit or placement of information</td>
</tr>
<tr>
<td>Four or more active ingredients</td>
<td>6 points / 6 point</td>
<td>Either on the front of pack if space</td>
</tr>
</tbody>
</table>
### Description of pack or label type

<table>
<thead>
<tr>
<th>Description of pack or label type</th>
<th>Active ingredient / strength font size</th>
<th>MIP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section (10)(8)(b)</td>
<td></td>
<td>permits or on the back of pack, as part of the MIP – this will allow Day &amp; Night products to include front of pack information as an option, in the same sized font that would be allowed on the back.</td>
</tr>
<tr>
<td>Other labels</td>
<td>10 point / 10 point</td>
<td>MIP required</td>
</tr>
</tbody>
</table>

### 6. Specific concerns – medicines information panel

The MIP as proposed has certain limitations:

- It is difficult to accommodate on many labelling types – including but not limited to wrap around bottle labels, bottle labels designed as separate front and back labels, small cartons with limited space on each panel, tubes, and the primary packs which enclose small containers (which are by nature also small). These pack sizes and types should be excluded from the requirement for the MIP due to space constraints. For these packaging types, there should be some requirement to group and order the information consistently; however this could be done in a more flexible way, by avoiding duplication and perhaps allowing smaller headings or other ways of accommodating the information.

- Products with lengthy warning statements have difficulty accommodating all of the required information. For these products that are required to present a considerable amount of information on a small space, while maintaining a high level of clarity and readability, performance based labelling design becomes even more important. Continuous improvement of label designs should be encouraged rather than discouraged by the TGO.

- The draft TGO 79 limits the information that is able to be included in the “Warnings” section to warning statements required by the TGA, e.g. in RASML or in any other standards, or required as a condition of registration or listing (see section 6, Interpretations). It is unclear whether additional warning statements proposed by sponsors – e.g. as part of global core data sheet updates – are allowed to be included in this section. The interpretation of “warning statements” in section 6 of the draft TGO 79 should be widened to include additional statements proposed by sponsors for inclusion on labelling.
• The MIP is proposed for all registered non-prescription medicines, and perhaps there should be exemption for certain classes of products from requiring the MIP. Examples are registered complementary medicines and hand sanitisers.

• Some labelling requires additional information that is not part of “Warning statements” – such as dosage tables and cautionary graphics such as the red diamond for flammable goods, and others. Some flexibility may be required at times for these products.

• It should be recognised that the back of pack also has space pressures, including the requirement for the full sized barcode for scanning in the grocery environment. Retailers do not accept goods without full sized barcodes.

• The USA and Canada require the MIP to be on the primary pack only, and it is not required on the immediate container when it is enclosed in a primary pack. Ego does not support a unique Australian requirement of requiring the MIP on the primary pack as well as the immediate container.

Below are some examples of labels that demonstrate some of these limitations more clearly.
6.1 Suitability for small labels / small containers that are not defined as small containers as per sections 10(14) & 10(15) of the draft TGO 79

Example 6: Wrap around bottle labels

The 100ml product is sold without a carton, so all the MIP information must be place on the single wrap around label. As can be seen below, the MIP does not fit on the label.
Example 7: Bottle labels designed as separate front and back labels with small dimensions.

While this product is 200ml, the bottle shape allows for a small label dimension on the front and back. As can be seen below, the MIP does not fit in the label space.
Example 8: Bottle labels designed as separate front and back labels with small dimensions.

The product below is 70ml however the bottle shape allows for only a small label dimension on the front and back. As can be seen below, the MIP does not fit in the label space.
Example 9: Small cartons with limited space on each panel

The carton for a 30g tube, as shown below, has very limited space. With the barcode needing to be full size and the heritage branding in place, the MIP cannot fit onto the remaining space.
Example 10: Tubes

The 30g tube below, which falls outside of the defined ‘small container’, must contain both the 15 pt actives and the MIP. Given the limited print space on a tube, it will never fit as illustrated below. For all this text to fit, the tube would need to be at least 100g in size.
Example 11:

For flammable goods above 150ml, the flammable diamond is required. However it is unclear from TGO79 where this should be located. As illustrated below, the only logical place we could put it would be within the ‘warnings’ of the MIP.

6.2 Ego proposals for changes to MIP requirements

Ego acknowledges that some initial concerns have been addressed in the draft TGO 79. These include the ability to continue the information over more than one panel if there is insufficient space, as well as allowing the use of colour for headings.

However, further amendments to section 10(20) are requested:

The MIP should be allowed to be truncated or amended, if space does not permit. Examples are: Removal of “Medicine Information” heading; removal of “ingredients” heading and active ingredient information if it is present on the main label; removal of “uses” if these are shown on the main label.

An additional category of “small OTC labels” [in addition to sections 10(14) and 10(15)] should be created, and these labels should have the option of using truncated or amended MIP (as described
above) to fit their labels. The definition of “small OTC labels” should be developed collaboratively with industry.

The definition of “Warnings” should be expanded to allow additional warning statements requested by sponsors that are not in RASML or a TGA standard, so that these may be added to the “Warnings” section of the MIP.

Some very low risk products such as hand sanitisers should not be required to have a MIP.

Ego supports the US and Canadian position, that the MIP should be required on the primary pack only (not on the immediate container if it is enclosed in a primary pack).


The preceding sections on active ingredient font size and the MIP have demonstrated that the increase in prominence of active ingredients on labelling, together with the MIP present a challenge and are unable to be accommodated on all registered non-prescription medicines.

In relation to non-prescription medicines, the draft TGO 79 proposes:

- For registered medicines - a minimum font size of equivalent to 15 points Arial in any sans serif font, unless the section (10)(14) or (10)(15) applies.
- For registered non-prescription medicines that have a MIP and when there are 4 or more ingredients, these may be declared on the front of pack.
- For products in small containers, less than or equal to 25 mL capacity, the active ingredient must be in a font size equivalent to 8 points Arial; the strength must be equivalent to 6 points Arial in any sans-serif font.
- For listed medicines, active ingredients and strengths must be equivalent to 6 points Arial in any sans-serif font.

As has been clearly shown, together with worked up examples, there are factors that are applicable to non-prescription registered medicines which make the font sizes proposed by the draft TGO 79 difficult, if not impossible to accommodate without either increasing carton / container dimensions or significantly affecting the size of branding or the intrusion onto registered trademarks. In addition, OTC medicines require consumer oriented information on the front of pack, to convey information that is important to consumers when choosing medicines. The following additional,
non-statutory information is almost always included on the main label of a non-prescription medicine, as it has been shown to be important to consumers at the point of sale:

- Branding information, brand logos, brand design or trademarks. These may assist with differentiation, particularly in the case of umbrella brands
- Information on what the product is used for – if there are multiple ingredients, this may be quite comprehensive
- Generic product information, e.g. “anti-inflammatory” “anti-fungal” etc
- Additional descriptors for the dosage form and description (may be a graphic, in the case of day & night)
- Other information – such as “sugar free”, whether a measure is included, graphics to assist consumers with limited literacy, etc.

The amount and type of information required on a prescription medicine is therefore very different to that needed on a non-prescription medicine.

The MIP has also been introduced as part of the draft Order, to introduce consistency in grouping and ordering of information. Ego supports consistency and grouping, on the provision that flexibility is shown to allow the information to be accommodated on as many types of packaging as possible without the need for S14 exemptions.

It is therefore evident that the draft TGO 79, by making exclusion provisions only for listed medicines, “small containers” and “very small containers” has essentially applied an active ingredient size as a “one size fits all” approach to both prescription and non-prescription registered medicines, without considering the specific requirements of non-prescription medicines.

Ego believes that this is unachievable, and requires change to acknowledge the particular information requirements on the main label of non-prescription medicines and the additional space requirements for the MIP.

Ego has recommended an approach based on available label space of the main label. In considering the various options, it was decided that surface area of the main label would be a suitable approach for the following reasons:

- It is not limited to bottles
- It considers both wrap around labels as well as separate front and back labels
• It considers cylinders, tubes, dispensers, and small cartons (eg for 2s packs, 12s packs, pocket packs)
• It achieves increased active ingredient prominence compared to status quo
• It allows some level of consistency in allowing an abridged MIP if needed

We therefore propose the following, in relation to all registered non-prescription medicines (including registered complementary medicines):

• Retain active ingredient font size proposed in the draft TGO 79 for small and very small containers [section (10)(14) & (10)(15)]
• Create an additional category of “intermediate registered non-prescription medicine” or “intermediate sized label”, which should be set at less than or equal to 70cm² for the main panel.
• For this category, the recommended font size for active ingredient and strength should be the equivalent to 8 points Arial in any sans serif font, and an abridged or truncated MIP should be allowed.
• For medicines that contain four or more active ingredients, the option of including these in the MIP (as per the draft TGO 79) OR on the main label in a font size of not less than 6 points Arial in any sans serif font, i.e. allow what is proposed in draft TGO 79 for the back panel to be included on the front panel – which would be acceptable to many sponsors of Day & Night composite packs.

As it is written, the TGO 79 draft is confusing and cumbersome to read. If it is implemented as is, it will require that a significant number of Ego’s products be resized. Ego has demonstrated, in this response, the unworkable nature of the TGO 79 proposals for our products, and has offered a number of suggestions that could be made to work. However, given the safety profile of topical products it is an unfair and unreasonable impost to require topical products to comply with the TGO 79 as written, and we propose they be exempted as has been done for sunscreens. Ego is happy to discuss any of our comments or suggestions further with the TGA.