Dear Sir/Madam,

Re: Medicine Labelling Consultation, August 2014.

Johnson & Johnson Pacific Pty Ltd (JJP) welcomes the opportunity to review and comment on the introduction of the new Therapeutic Goods Order 79.

JJP is a marketer of a wide range of OTC registered and listed medicines including sunscreens comprising of 135 products. JJP is also a member of Australian Self Medication Industry (ASMI) and the New Zealand Self Medication Industry Association (NZSMI) and Accord. JJP fully endorses the submissions provided by these associations.

JJP has reviewed and provides a response to each of the consultation documents:

- Regulation Impact Statement (RIS) – General requirements for labels for medicines
- Therapeutic Goods Order (TGO) No 79 – Standard for the labelling of medicines
- Guideline on Medicine Labelling

The details of our reviews are included in Parts A, B and C of this submission.

We also refer the TGA to the submission made by JJP on the 24th August 2012 for the initial consultation of the medicine and labelling reforms released by the TGA in May 2012. There is information in the 2012 submission that remains relevant for the current submission, despite the fact that the proposals put forward by the TGA are different.

Executive Summary

JJP is supportive of any initiative that embraces the principles of quality use of medicines and will result in the safer use of medicines, consistent with J&J’s Credo.

While the TGA’s proposals provide recommendations on regulatory changes to the labelling requirements for medicines, there is however a distinct lack of evidence that the proposed changes will result in better health outcomes and reduced consumer confusion.

The impact of the implementation of proposal 3 of the TGA’s RIS: Introduction of a new Therapeutic Goods Order (TGO 79) as detailed in the consultation documents, will result in radical changes to
most medicine labels, is unlikely to deliver the expected benefit to consumers, will be extremely
costly to industry and have a profound and far reaching effect on the operations of OTC companies
during implementation, the cost benefit of which we believe has not been adequately substantiated
especially in relation to OTC medicines.

We believe that the proposed changes should be considered more thoroughly in the Australian
context, taking into account the diversity of the products regulated as medicines and be measured
against tangible goals so that the cost of the changes can be accounted for. **JJP strongly encourages
the TGA to consider undertaking appropriate consumer research, using validated methodology to
ensure the proposed changes to the legislation will have the desired effect and will not result in a
retrograde step.**

Our key concerns are as follows:

1. **Regulation Impact Statement (RIS) – General requirements for labels for medicines**

   **1.1 Cost: The RIS estimated costs and assumptions are not adequate**
   The impact of implementation of TGO 79 on JJP has been estimated to be approximately $7.3
   million. The details of each cost and the assumptions used in arriving at this cost estimation is
   provided in Section 3 of Part A. Based on our estimations of indirect and direct costs associated with
   the proposal in relation to the JJP OTC business we can see that the costs enumerated in the TGA’s
   RIS does not represent our business or other OTC businesses of a similar size.

   Label changes and control of label changes involve several departments within JJP and associated
   third party contract organisations. The estimated cost impacts to implement the changes in the draft
   TGO 79 for the different departments are as follow:

<table>
<thead>
<tr>
<th>Department/Function</th>
<th>Total Cost (AUD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand Marketing</td>
<td>$1,265,691</td>
</tr>
<tr>
<td>Graphic Artists &amp; Design Consultants</td>
<td>$452,800</td>
</tr>
<tr>
<td>Regulatory Affairs</td>
<td>$993,329</td>
</tr>
<tr>
<td>Technical Services</td>
<td>$128,644</td>
</tr>
<tr>
<td>Quality Assurance</td>
<td>$173,292</td>
</tr>
<tr>
<td>Supply Chain</td>
<td>$199,190</td>
</tr>
<tr>
<td>Sales &amp; Trade Marketing</td>
<td>$795,690</td>
</tr>
<tr>
<td>Consumer Care/Call Centre</td>
<td>$30,259</td>
</tr>
<tr>
<td>Manufacturing</td>
<td>$1,878,500</td>
</tr>
<tr>
<td>Project Management</td>
<td>$182,832</td>
</tr>
<tr>
<td>Finance</td>
<td>$45,648</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>$7,376,250</strong></td>
</tr>
</tbody>
</table>

   *To account for any unaccounted costs (includes but is not limited to price increases, write-off
costs of unused raw materials and additional resource costs) an additional 20% has been included
as a contingency plan.

   Based on the limited cost breakdown provided in the TGA’s RIS and the cost conclusions it is evident
that the cost impact has not been adequately considered for industry to implement the required
changes as outlined in the draft TGO 79.
We understand that the assumptions made in the TGA’s RIS were based on the average figures provided by an independent survey in 2014 of 9 companies covering prescription, OTC and complementary medicines. This is clearly an inadequate sample size on which to base cost estimates for decision making purposes given the huge variation in size, culture and practices of businesses across the each medicine sector. **The financial impact of the proposed new labelling is profound and grossly underestimated in the TGA’s RIS.**

As such the assumptions made in arriving at the cost estimates provided in the TGA’s RIS and in arriving at the cost estimates provided in Part A by JJP are very different. The assumptions made in the TGA’s RIS are not sufficiently comprehensive and are not reflective of the practices of industry.

JJP provides the following comments on some key assumptions made in the RIS:

<table>
<thead>
<tr>
<th>RIS Assumption</th>
<th>JJP Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>More than half of medicine labels are changed every three years</td>
<td>Changing brand design is complex, risky and expensive. Brand redesign for commercial reasons only occurs once every 6-10 years, potentially longer. Hence the majority of our medicine labels will require changes outside normal business activity to meet the requirements of the TGO 79.</td>
</tr>
<tr>
<td>In many cases changes would be incorporated with other label changes.</td>
<td>This is a desirable situation however given the low turnover of labels in our OTC business instigated for commercial reasons is likely to occur a lot less often than assumed by the RIS. Similarly it is not always possible to hold back or move up implementation of changes and movability of a change will depend on each individual situation.</td>
</tr>
<tr>
<td>The indirect costs to industry include the labour involved in preparing a variation to the ARTG entry and also the costs to produce a new label.</td>
<td>The changes required by the TGO 79 require extensive label redesign for registered OTC products. As detailed in Part A label changes and control of the label changes into production and distribution involve many internal and external personnel. We believe that the indirect costs to industry have been grossly underestimated for OTC businesses of a similar size to JJP.</td>
</tr>
</tbody>
</table>
| Wage rates for the preparation of the application are $42 per hour | The complexity of the project will require experienced staff and managerial input. Industry standard salaries are:  
  - Senior Associate: $89.15/hour  
  - Manager: $100.25/hour  
If external consulting help is required then costs per hour range from $150 - $300. |
| Estimated pre-production costs for ‘minor and ‘medium’ level label changes, range from $900 to $1937 | Based on our estimation, the cost to obtain new printing plates at the manufacturing sites alone equates to approximately $2762 per label vs the RIS estimate of pre-production costs of up to $1937 per label. We believe that the costs to industry have been grossly underestimated for OTC businesses of a similar size to JJP. |
Additional assumptions that have been taken into account in the JJP estimates but do not appear to have been taken into account in arriving at the RIS cost estimate are:

- Consequential label change application costs to Medsafe for trans-Tasman products.
- It is unclear to whether one label per product has been assumed in the RIS. Many JJP products have separate front and back container labels and many containers are further packaged into a carton or other outer packaging.
- Many OTC products come in a number of pack sizes which, due to the difference in container size, will require complete label design consideration as opposed to a change in the strength (the prescription example included in the TGA RIS where it is assumed considerably less work/cost is incurred for second, third etc strength products in the range).
- The additional complexity incurred in implementing the proposed changes across a number of different suppliers in several different countries.

1.2 Safety: The evidence provided in the RIS is not sufficient to demonstrate that the label changes required by the TGO 79 will achieve the objective to reduce the risk of the safety issues for the use of OTC medicines

We consider that the information provided in the RIS is not sufficient to demonstrate that the label changes required by the TGO 79 will achieve the objective to reduce the risk of the safety issues for the use of OTC medicines in Australia or that current OTC medicine labels generally are a safety issue for the following reasons:

- The information is based largely on studies in the literature concerning issues with prescription medicines or are US studies which are not representative of the Australian OTC environment.
- The US studies demonstrate that there are consumers that have difficulties with comprehending the US Drug Facts panel on which the proposed Medicines Information Panel is based.
- The current use of performance based style OTC labelling in Australia is not considered.
- No local data appears to have been generated to evaluate the changes required by TGO 79.

Given the consumer safety is at stake and the huge cost impact that the TGO 79 will have on industry it is absolutely critical upon government to conduct local research into consumer medicine label comprehension before implementing any changes. Additionally, the success (or lack thereof) of the proposed changes in meeting the desired outcome should be measured and reported to the general public.

2. Therapeutic Goods Order (TGO) No 79 – Standard for the labelling of medicines
JJP currently supplies OTC medicines to both Australia and New Zealand in harmonised labels and would be greatly aggrieved if changes to the labelling requirements prevented joint labelling with
New Zealand. In fact, such an outcome could result in New Zealand consumers being denied several of our products due to costs in providing unique labels to each market. This is a disappointing development given that efforts were being made to align the regulatory requirement in both countries with the view that there will be a single trans-Tasman agency, ANZTPA.

We request a commitment from TGA to attain an alignment with Medsafe on the proposed changes to the labelling order so that labels can remain harmonised in New Zealand.

JJP comments and proposals for amendment are provided by line number in Part B.

The areas with which JJP has specific major concerns are outlined below:

2.1  Expression of Active ingredients on OTC medicine labels

2.1.1 Salt/Hydrate name and Quantity statement (lines 607 – 608 of the draft TGO 79)
The TGO 79 requires that labels include on the front/main panel the names of active ingredients, where the interpretation of the “name of the active ingredient” is the Australian Approved Name (AAN) for that ingredient.

OTC medicines are lower risk medicines for which precise dosing is not an issue. JJP believes that the inclusion of the salt or hydrate as per the AAN:

- Does not benefit consumers and is potentially confusing where different salts are used for the same active moiety (e.g. Sodium Ibuprofen Dihydrate vs. Ibuprofen Lysine vs. Ibuprofen (free acid)).
- It is not important to consumers or healthcare professionals needing to know what other OTC medicines a consumer is taking. For many consumers it is hard enough to recognise/remember ingredient names as opposed to complex names that include salts/hydrates.

The TGO 79 also requires that labels include on the front/main panel the quantities of active ingredients. In the case of ingredients that are included as salts or hydrates the expression of the ingredient quantity as it’s salt or hydrate as opposed to its active pharmaceutical moiety can result in apparent differences in strength where there are none; e.g. ‘Phenylephrine Hydrochloride 5mg’ would appear stronger than ‘Phenylephrine 4.2mg’, when both ingredients are pharmacologically equivalent.

JJP proposes that:

- The salt or hydrate component of an active ingredient name be excluded from the main label where that component does not contribute to the pharmacological action of the product.
- The requirement of the quantity statement of the active ingredient on the main label be removed as this information will be available in the Medicine Information Panel on the back panel.
Where the same medicine is provided in more than one strength, a description relating to
the strength of the active ingredient could be included on the main label; e.g. ‘EXTRA
STRENGTH’.

2.1.2 Font Size (lines 646 – 649 of the draft TGO 79)
The TGO 79 requires that the name and quantity of the active ingredient of a registered OTC
medicine appear in a text size equivalent to at least 15 point Arial (approximately 4 mm).

JJP believes that the proposed requirement for a 15 point font size for the name and quantity of the
active ingredients on the primary label panel does meet the intended objective of helping the
consumer to identify the active ingredient in the medicine and is not a practicable requirement for
registered OTC medicines for the following reasons:

- If the font size is increased from 6 point (current) to 15 point, the text becomes increasingly
  more cluttered and potentially more difficult to read and often does not fit within the the
  size of the existing panel.

- Where products contain more than two active ingredients, it would be even more difficult
  for sponsors/manufacturers to comply with the requirements of subsection 9(7).

- In order to meet the requirement of the 15 point Arial font size other information important
  for consumer selection (e.g. graphic representation of symptom(s) the product relieves, pack
  size), may have to be removed from the main panel.

- Product claims and attributes on the main panel are important as they help the consumers
  to self-select non-prescription medicines.

- The expression of the pack size on the main panel is a requirement of the National Trade
  Measurement legislation and cannot be removed without changes to this legislation.

The proposal to require a 15 point font size for the name and quantity of the active ingredients on
the primary label panel in many cases will not be achievable and will require major artwork redesign.
The requirement presents an even more difficult situation for primary packaging of current OTC
products that are classified as ‘small containers’ as the primary packaging generally is of similar size
as the small container.

JJP proposes that:

- The proposed requirement of 15 point font size is reduced to 10 point font for active
  ingredient names for registered OTC medicines where the salt name and quantity of the
  active ingredient is not required. We believe this font size would be more easily adaptable to
different sizes and shapes of containers, ensure that the active ingredient name is
prominent and at the same time remain clearly legible.

- The proposed requirement of 15 point font size be reduced to 8 point font for active
  ingredient names for registered OTC medicines where it is necessary to include the salt and
  quantity of the active ingredient on the main panel; e.g. antacids.
That where a medicine is packaged in a ‘small container’, the active ingredients listed on the corresponding main label of the primary pack should allow for a font size of 8 point Arial.

2.2 Medicine Information Panel (MIP) (Line 1108ff of the draft TGO 79)
JJP supports the principle behind a standardised format for the back of pack, however there are concerns that the format is not the optimal format for consumers. The concerns are summarised below:

- Label comprehension studies in Australian consumers have not been performed on the proposed MIP format.
- The information to be communicated about OTC medicines varies with different types of medicines and therefore one solution does not necessarily fit all.
- There is no provision to optimise the label based on consumer testing or feedback.
- The US FDA requirements for the ‘Drug Facts’ panel (on which the proposed MIP is based) has been found lacking (refer to JJP’s detailed response to Therapeutic Goods Order (TGO) No 79 – Standard for the labelling of medicines line 1108).

Again, JJP strongly encourages the TGA to consider undertaking some consumer research, using validated methods to ensure the proposed changes to the legislation will have the desired effect and will result in best in class labelling for non-prescription medicines.

2.3 Small packs (Lines 407-408; 1116 – 1126 of the draft TGO 79)
The current TGO 79 definition of a “small container” is a pack size of not more than 25mL and under section 10(14) is afforded some concessions in labelling requirements based on the proviso that the primary packaging of the container meets the full requirements.

This definition only considers liquid preparations and fails to consider that if the container is small, any primary packaging is consequently also small in size (e.g. carton containing a small bottle).

Meeting the requirements for labelling for such products has always been a challenge, such that the proposal to increase the font size to 8 point on the small container and the addition of the MIP on the small container primary packaging would become problematic.

JJP has spent considerable time and resources drafting labels using the proposed requirements and found that products such as an 80mL mouthwash or a 100mL cough syrup are also unable to meet the proposal however they can be made to meet the requirements under small containers.

JJP proposes that the definition of “small container” would more appropriately be defined as a pack size of not more than 100mL.

3. Guideline on medicine labelling
JJP has reviewed the TGA Guideline on Medicine Labelling and our comments are provided in Part C.

Any changes made to the proposed TGO 79 as a result of this consultation needs to be reflected in this guideline.
4. **Concluding Comments**

JJP cares deeply about its responsibilities to consumers and healthcare professionals and would welcome a well-founded proposal to regulate medicine labelling that will improve Medicine safety and the quality of use of medicines.

We understand governments need to implement improved labelling requirements and that medicine labelling has been an open issue for quite some time. Unfortunately during this time there appears to have been no robust original research in the area of medicine labels for non-prescription medicines in Australia. Consumer label comprehension studies must be used to validate the health outcomes required by the TGA.

JJP believes that implementing the proposed TGO 79 “as is” would be a backward step for the consumer and may result in a label that performs worse than the current label designs. Comparative label comprehension studies of the proposed OTC medicine label, comparing against current performance based labels must be undertaken. JJP implores the committee to consider seriously the suggestions for the changes that have been made by the TGA in the draft TGO 79.

JJP has spent a considerable amount of time exploring the costs and developing solutions to help the TGA reach its objectives. We believe that the cost assumptions behind the proposal are neither comprehensive nor representative of the OTC industry. Implementation the changes will be extremely expensive and disruptive. We found that for many labels the requirements cannot be achieved without significant label redesign interfering with other important label elements or resizing of labelling/packaging.

Given the huge cost impact that the TGO 79 will have on industry it is beholden upon government to be accountable for the veracity of the changes and to put measures in place against tangible goals so that the promised improvement in safety brought about by the changes do occur and can be measured.

Should you require any additional information please do not hesitate in contacting me.
Part A
Regulatory Impact Statement:
General Requirements for Labels for Medicines

1 Table of Contents
2 Overview

This document contains the business impact to Johnson & Johnson Pacific (JJP) as a result of the proposed changes proposed in the draft TGO 79.

Johnson & Johnson Pacific Pty Limited (JJP) has identified that the changes proposed in the draft TGO 79 are likely to impact:

- 28 Brands
- 125 distinct registrable products
- 10 distinct listable products
- 210 individual SKUs
- 400 labels (including but not limited to tubes, cartons, foils, bottle labels)
- 280 Shippers and Shelf Ready Packaging (SRPs)

The business impact has been assessed on these figures. The impact has been broken down into various functions within JJP and is presented in the following sections. A number of assumptions have been made to be able to estimate the business impact. The assumptions that are made are highlighted within the functional breakdown.

There are a set of assumptions that are made that are common to all functions. These are outlined below. The assumptions made may not necessarily represent the actual situation at the time of implementation of the TGO 79.

1. There are no changes to the number of products impacted by the proposed changes.
2. Costs are fixed and are not subject to inflation.
3. Personal/resource cost is based on the following set of criteria below on a per annum basis (assumes wages are uniform across functions and a manager is an existing resource).

   a) Senior Associate
      - Base Salary: $100,000
      - Performance/Contract completion bonus, target 10%: $10,000
      - Superannuation @ 9.5%: $10,450
      - Contractor agency fee @ 25% total remuneration package (a+b+c): $30,112
      - On costs/employee/recruitment costs @10% remuneration package: $12,045

   b) Total Annual (assumes 48 wks/yr): $162,607
      - Total Per week (assumes 38 hrs/wk): $3388
      - Total per hour: $89.15
Manager

a) Base Salary
$138,000

b) Performance/Contract completion bonus, target 10%
$13,800

c) Superannuation @ 9.5%
$14,421

d) On costs/employee costs @10% remuneration package
$16,622

Total
$182,843
Annual
$3809
Total Per week (assumes 48 wks/yr)
$100.25

An explanation of the impact, as detail per function is provided in the following sections.
3 Business Impact for Johnson & Johnson Pacific Pty Ltd

3.1 Brand Marketing

3.1.1 Function

Brand Marketing serve as brand custodians. They ensure that the brand equity is preserved with any change, launch or marketing strategy that is put into place to promote the brand.

The change that has been proposed under the draft TGO 79 is likely to have a profound impact on brand equity and imagery, and as a result will have a significant role to play in the updating of any artwork, labels or marketing collateral that result from the proposed changes.

3.1.2 Assumptions

In the JJP portfolio there are 28 brands that will be impacted by the proposed changes. Of these 28 brands, it is assumed that there are 9 keys brands.

The assumptions are that:

1. The strategic focus will remain on the 9 key brands and does not increase.
2. The 9 key brands are supported with above the line advertising.
3. The times estimated are an average. It is acknowledged that some activities will be shorter than stated. Equally some activities may take longer than quoted.
4. Any advertising that is updated as a result of the packaging changes are for pack shot changes only. The cost assessment does not include having to redesign brand imagery to ensure compliance with the proposed changes under the draft TGO 79. Assumes that the TVCs do not require changing for commercial advantage.
5. The costs to dispatch revised Ads in New Zealand have not been included.

3.1.3 Impact

3.1.3.1 Resource (People) Impact Assessment

Change Control

With any change to artwork, a change control must be reviewed and approved by Brand Marketing.

Review and approve change controls

1 3 5 products @ 10 minutes per change control
2 2.5 Hours

Artwork Approval

...
All changes to artwork must be reviewed and approved by Brand Marketing in line with company SOPs.

Changes as proposed in TGO 79 are likely to have a profound impact on the look and feel of the brand identity. Changing brand design is complex, risky and expensive. Brand redesign for commercial reasons would only occur once every 6-10 years, potentially longer. The design changes are often subtle and not significant due to the potential for eroding brand equity.

Writing of briefs: 9 brands @ 10 hours per brand

Internal alignment on brief: 9 brands @ 5 hours per brand

Briefing of agencies: 9 brands @ 2 hours per brand

Internal alignment on agency output: 9 brands @ 6 hours per brand

207 Hours

Project Time

It is difficult to estimate the total time required for project management of the changes. An additional 15% is being allowed to facilitate the additional unaccounted time.

15% Total hours of change control, artwork and consumer research

238.4 Hours

A total 1827.9 hours will required by Brand Marketing to implement the proposed changes as outlined in TGO 79.

3.1.3.2 Cost Assessment

Consumer Research

Changes as proposed in TGO 79 are likely to have a profound impact on the look and feel of the brand identity. Changing brand design is complex, risky and expensive. Brand redesign for commercial reasons would only occur once every 6-10 years, potentially longer. The design changes are often subtle and are not significant due to the potential for eroding brand equity.
Changing Advertising

Most pieces of advertising include pack shots of the product. With a change to the pack designs, all advertising that includes pack shots will need to change to ensure pack shots displayed in the advertisement are consistent with the product available at retail.

Assumptions made are that 9 brands out of 28 are supported above the line, with 2 ads (30 second and 15 second) each. Costs are an average cost based on using rotoscope to make the changes in TV commercials (TVCs).

- **Rotoscope changes to pack shots**
  - 18 Ads @ $5,000 per Ad
  - $90,000
Dispatching of revised TVCs
18 Ads @ $2,000 per dispatch

Updating out of home material, exclusive of billboards
9 brands @ $1,000 per brand

$36,000
$9,000

$135,000

It is estimated that there will be a financial impact in the vicinity of $1,066,500 to the Brand Marketing function to facilitate research and update existing creative and marketing material once the changes proposed as outlined in the draft TGO 79 are implemented.

3.1.4 Summary
The direct and indirect impact to the Brand Marketing function at JJP has been assessed based on the implementation of the draft TGO 79. The impact considers requirements from a resource perspective (work hours) and from a financial perspective.

From a financial perspective, it is estimated that the impact the Brand Marketing function will be in the vicinity of $1,066,500 (exclusive of resource).

From a resource perspective, it is estimated that a total of 1827.9 hours will be used to implement the changes. Assuming that 1 work week is 38 hours, this equate to 1 Full time employee for 1 year (48 working weeks).

A senior associate would be required for the work to be completed. Additionally, it is estimated that there would be managerial oversight of the senior associate, potentially accounting for 20% of the manager's time.

From a resource perspective this will cost:
48 weeks @ $3388 per week – equates to $162,624
20% managers time: 9.6 weeks @ $3809 per week - equates to $36,567

Total Resource cost - $199,191.

A combined total for resource and direct financial impact for the Brand Marketing function at JJP equates to $1,265,691.
3.2 Graphic Artists and Design Consultants

3.2.1 Function
JJP utilises external graphic artists to design new, and make changes to existing artwork and labels. This is not an in-house function; therefore there will be no resource impact on JJP.

3.2.2 Assumptions
In determining the impact the following assumptions will be made.

1. All products are Trans-Tasman and that the changes proposed by TGA are acceptable to Medsafe.
2. The rates charged by the graphic artists do not increase.
3. Shippers and SRPs require less time than primary and secondary labels.
4. There are a total of 680 pieces of artwork to be altered as a direct or indirect result of the proposed labelling order. Of the 680 pieces of artwork, 280 pieces account for the SRPs and shippers.

3.2.3 Impact
Artwork Design
It is assumed that the changes to each existing piece of artwork will be significant and is likely to involve at least 2 revisions.

Negotiated rate for complex & significant artwork, inclusive of revisions
400 pieces of artwork @ $950 per artwork (inclusive of GST)

Negotiated rate for less complex artwork, inclusive of revisions
280 pieces of artwork @ $260 per artwork (inclusive of GST)

$380,000
$72,800
$452,800

3.2.4 Summary
The direct cost to JJP has been assessed for the proposed changes to the labelling order. This impact is purely financial as all graphic related work is outsourced to an appropriately qualified agency.

The estimated financial impact for JJP relating to the design and completion of artwork resulting from the change to the labelling order equates to $452,800.
3.3 Regulatory Affairs

3.3.1 Function

The Regulatory Affairs function will be responsible for the design of the revised labels complying with the revised labelling order. As this change is initiated by the regulator, there is an expectation that the Regulatory Affairs team will lead the project and initiate all necessary internal change controls, and be part of the design, review and approval of all pieces of artwork that are either directly or indirectly impacted by the revised labelling order.

The Regulatory Affairs function will also be responsible for the compilation of the submissions to the regulators (both TGA and Medsafe) as the JJP products are harmonised for the purposes of marketing in both Australia and New Zealand. This will include the authoring of the necessary CTD sections, publishing and completion of the submission forms as required by each regulator, filing and maintenance of internal databases and systems for internal compliance.

3.3.2 Assumptions

In determining the impact the following assumptions will be made.

1. The times estimated are an average. It is acknowledged that some activities will be shorter than stated. Equally some activities may take longer than quoted.
2. The labelling changes proposed in TGO 79 have been aligned and accepted by Medsafe.
3. All products are Trans-Tasman and require submissions to both TGA and Medsafe.
4. 125 products are registrable and will require submission and evaluation by the TGA and Medsafe.
5. 10 products are listable and do not need to be submitted to with TGA or Medsafe (however, internal requirements remain the same).
6. The TGA will not permit a fee exemption for submissions made to bring existing products into compliance with the revised labelling order.
7. Assumes submissions cannot be grouped (the reasons behind this might relate to product schedules, limiting write offs of already existing packaging components).
8. Assumes that all submissions will be C2 changes in both Australia and New Zealand.
9. Assumes the fee as of June 2014 does not increase or change to a new fee structure for Australia or New Zealand.
3.3.3 Impact

3.3.3.1 Resource (People) Impact Assessment

Change Control

With any change to artwork, a change control must be reviewed and approved by Regulatory Affairs. Change controls will be raised by Regulatory Affairs. Raise and approve change controls for 135 products @ 20 minutes per change control.

Artwork Approval

All changes to artwork must be reviewed and approved by Regulatory Affairs in line with company SOPs (include initiating, reviewing and approving). Review and approve all labels and artwork for 680 pieces of artwork @ 3 hours per artwork.

Submission Preparation

The preparation of submissions for both Australia and New Zealand based on the fact that all products are market. Prepare and submit label changed submission for Australia 125 submissions @ 1 hr per submission. Prepare and submit label changed submission for New Zealand 125 submissions @ 1 hr per submission.

Internal systems and database update for non-submitted changes (listables) 10 updates @ 0.5 hr per update.

Total Hours 2040 + 255 + 125 = 2420 Hours

Project Time

It is difficult to estimate the total time required for project management of the changes. An additional 15% is being allowed to facilitate the additional unaccounted time. 15% Total hours of change control, artwork and submission time 2420 * 1.15 = 2773 Hours

A total 2691 hours will required by the JJP Regulatory Affairs function to implement the proposed changes as outlined in TGO 79.
3.3.3.2 Cost Assessment

Submission Costs

Submission costs are based on each change being classified as a C2 change in both Australia and New Zealand. Does not allow for the annual fee increase or the potential for combining submissions. The costs do not allow for courier or stationary costs.

Cost for C2 Change for Australia

125 submissions @ $4935 per submission

Cost for C2 Change for NZ

125 submissions @ $720 (NZL) per submission

Allow for an average exchange rate of $1 AUD = 1.10 NZL, $616,875 $90,000 $81,818 $698,693

A total of $698,693 will be required for submissions. This figure does not allow for the annual fee increase by the TGA.

3.3.4 Summary

The direct and indirect impact to the regulatory affairs function at JJP has been assessed based on the implementation of the draft TGO 79. The impact considers requirements from a resource perspective (work hours) and from a financial perspective.

From a financial perspective, it is estimated that the impact the marketing function will be in the vicinity of $689,693 (exclusive of resource).

From a resource perspective, it is estimated that a total of 2317.5 hours will be used to implement the changes. Assuming that 1 work week is equivalent to 38 hours, this equates to 1 Full time employee for a period of 1.48 years (71 weeks) based on 1 year being equal to 48 working weeks.

A senior associate would be required for the work to be completed. Additionally, it is estimated that there would be managerial oversight of the senior associate, potentially accounting for 20% of the manager's time.

From a resource perspective this will cost:

71 weeks @ $3388 per week – equates to $240,548

20% managers time: 14.2 weeks @ $3809 per week – equates to $54,088

Total Resource cost – $294,636

A combined total for resource and direct financial impact for the Regulatory Affairs function at JJP equates to $993,329.
3.4.1 Function

Technical Services is the function that is responsible for support the manufacture and marketing of products from a technical perspective. As a part of the proposed changes in the draft of TGO 79, the Technical Services function will be required to update all technical documentation including but not limited to specifications and codes relating product labelling.

3.4.2 Assumptions

In determining the impact to the Technical Services function, the following assumptions will be made:

1. The times estimated are an average. It is acknowledged that some activities will be shorter than stated. Equally some activities may take longer than quoted.

2. New SAP codes will be created for all 135 products (SAP is a GMP validated inventory & logistic system) to ensure the products with new artwork can be identified and tracked.

3. Universal Buying Forms (UBF) will need to be updated as a result of new SAP codes.

4. Barcodes will not require changes.

5. 10% of SKUs are reworked and have some form of secondary packaging process (eg over labelling/stickering) performed locally after it is received from the manufacturer.

6. 20 products are sourced from a European manufacturer which requires artwork to be uploaded into their artwork system called Epackmat.

7. No changes in label dimension or container sizes will be required.

3.4.3 Impact

Change Control
With any change to artwork, a change control must be reviewed and approved by the Technical Services function.

Change control approval
135 change controls @ 20 minutes per approval
Change control closure
135 change controls @ 10 minutes per approval
45 hours
22.5 hours
90 Hours
Communications

Technical Services is responsible for obtaining new packaging component codes from the manufacturer for every label.

Liaising with manufacturers

680 labels @ 3 minutes per label

34 Hours

Artwork Approval

All changes to artwork must be reviewed and approved by Technical Services in line with company SOPs.

Review and approve all labels and artwork

680 labels @ 1 hour per artwork

Uploading and approving labels into Epackmat (third party manufacturers artwork approval system)

20 products @ 1.5 hour per product

Review of printing proofs from manufacturers

680 labels @ 3 minutes per label

3.7 Hours

Documentation

New packaging batch records will be generated for every product.

Review and approval of batch records provided by the manufacturing sites

135 documents @ 5 minutes per approval

SKUs that are locally reworked will require the work instructions to be revised.

Revising local rework instructions

21 documents @ 1 hour per document

Technical Services is involved in the process of updating Universal Buying Forms (UBF). The UBF contains all the relevant data required by retailers / wholesalers.

Revising UBFs

210 SKUs @ 15 minutes per revision

Technical Services is responsible for updating Consumer Product Information Form. The CPIF is used by the Consumer Care/Call Centre to answer any questions raised by consumers.

Revising CPIFs

135 products @ 0.5 hours per revision

11.25 hours

21 hours

52.5 hours

67.5 hours
SAP Codes

Technical Services is involved in the process for SAP code change. Review and provide input into SAP code change for each product.

22.5 Hours

Project Time

It is difficult to estimate the total time required for project management of the changes. An additional 15% is being allowed to facilitate the additional unaccounted time.

15% Total hours of change control, communications, artwork approval, documentation and SAP codes

151.9 Hours

A total 1164 hours will be required by the JJP Technical Services function to implement the proposed changes as outlined in TGO 79.

3.4.4 Summary

The direct and indirect impact to the Technical Services function at JJP has been assessed based on the implementation of the draft TGO 79. The impact considers requirements from a resource perspective (work hours).

From a resource perspective, it is estimated that a total of 1164 hours will be used to implement the changes. Assuming that 1 work week is 38 hours, this equates to 1 Full time employee for 31 working weeks.

A senior associate would be required for the work to be completed. Additionally, it is estimated that there would be managerial oversight of the senior associate, potentially accounting for 20% of the manager's time.

From a resource perspective this will cost:

31 weeks @ $3388 per week – equates to $105,028

20% managers time:  6.2 weeks @ $3809 per week - equates to $23,616

Total Resource cost – $128,644.

The total resource impact for the Technical Services function at JJP equates to $128,644.
3.5 Quality Assurance

3.5.1 Function

Quality Assurance (QA) is the function that is responsible for ensuring products are manufactured (including but not limited to Manufacturing process, packaging, labelling and testing) to comply with the details registered with the regulator for all products.

As a part of the proposed changes in the draft of TGO 79, the QA function will be required to update all documentation that will be impacted as a result of the change in labels. This includes but is not limited to updating to specifications in the J&J Quality Assurance validated document control system and Product Release documentation. Additionally, as part of internal procedures, the products with new labels will need to be audited to ensure they meet internal and external requirements prior to the release of the product to the market.

3.5.2 Assumptions

In determining the impact to the QA function, the following assumptions will be made:

1. The times estimated are an average. It is acknowledged that some activities will be shorter than stated. Equally some activities may take longer than quoted.
2. New SAP codes will be created for all 135 products (SAP is a GMP validated inventory & logistic system) to ensure the products with new artwork can be identified and tracked.
3. There are a total of 680 pieces of artwork to be altered as a direct or indirect result of the proposed labelling order. Of the 680 pieces of artwork, 280 pieces account for the SRPs and shippers.
4. There are a total of 135 batch records to be revised as a result of the proposed labelling order.
5. 10% of SKUs are reworked and have some form of secondary packaging process (eg over labelling/stickering) performed locally after it is received from the manufacturer.
6. The changes proposed under the draft TGO 79 is classified as a 'major change' in JJP as the change will be perceivable by the consumer.

3.5.3 Impact

Change Control

With any change to artwork, a change control must be reviewed and approved by the QA function.

Change control approval (3 QA approvers in the process)

3 x 135 change controls @ 10 minutes per approval

Change control closure (1 QA approver in the process)

67.5 hours
General Requirements for Labels for Medicines

Documentation
New packaging batch records will be generated for every product.

Review and approval of batch records provided by the manufacturing sites
21 documents @ 10 minutes per approval

SKUs that are locally reworked will require the work instructions to be revised.

Review and approval of local rework instructions
21 documents @ 10 minutes per approval

Uploading rework instructions, batch records and artwork labels into GSS (a QA validated document control system used by Johnson & Johnson).

Uploading of documents 836 entries @ 1.5 minutes per entry

Approval of GSS specifications 836 specifications @ 15 minutes per approval

Product Release
With any artwork change a ‘First Article Inspection’ is required.
The inspection is performed on the first batch of production with the new labels.

Review and approval of samples against approved artwork labels in GSS
210 SKUs @ 30 minutes per approval

Administration – includes creating new document record folders, inclusive of trend cards, specifications and required checks
135 products @ 1 hour each

All major changes will require a full ‘Marketing Authorization Review’ prior to the release of products into the market.

Marketing Authorization Review – includes document generation and approval
135 products @ 3 hours per MAR

Total: 645 hours
SAP Codes

QA is involved in the process for SAP code change.

Master data creation 135 codes @ 1 hour per SAP code

135 Hours

Project Time

It is difficult to estimate the total time required for project management of the changes. An additional 15% is being allowed to facilitate the additional unaccounted time.

15% Total hours of change control, documentation, product release and SAP codes

206.7 Hours

A total 1585 hours will required by the JJP Quality Assurance function to implement the proposed changes as outlined in TGO 79.

3.5.4 Summary

The direct and indirect impact to the Quality Assurance function at JJP has been assessed based on the implementation of the draft TGO 79. The impact considers requirements from a resource perspective (work hours).

From a resource perspective, it is estimated that a total of 1585 hours will be used to implement the changes. Assuming that 1 work week is 38 hours, this equate to 1 Full time employee for 42 working weeks.

A senior associate would be required for the work to be completed. Additionally, it is estimated that there would be managerial oversight of the senior associate, potentially accounting for 20% of the manager's time.

From a resource perspective this will cost:

42 weeks @ $3388 per week – equates to $142,296

20% managers time: 8.4 weeks @ $3809 per week - equates to $31,996

Total Resource cost - $174,292.

The total resource impact for the Quality Assurance function at JJP equates to $174,292.
3.6 Supply Chain

3.6.1 Function
Supply Chain is the function that is responsible for the planning and management of all activities involved in sourcing and procurement, conversion, and all logistics management activities. The function is also responsible for the coordination and collaboration with channel partners, which can be suppliers, intermediaries, third-party service providers, and customers.

The changes that have been proposed under the draft TGO 79 is likely to have a major impact to the Supply Chain function due to the large number of different manufacturers and suppliers used by JJP.

The supply chain function will need to liaise with all the manufacturing sites and distributors to ensure the products with new artwork have been implemented and supplied to the Australian market with minimal disruption.

3.6.2 Assumptions
In determining the impact to the Supply Chain function, the following assumptions will be made:

1. The times estimated are an average. It is acknowledged that some activities will be shorter than stated. Equally some activities may take longer than quoted.

2. New SAP codes will be created for all 135 products (SAP is a GMP validated inventory & logistic system) to ensure the products with new artwork can be identified and tracked.

3.6.3 Impact
Change Control

With any change to artwork, a change control must be reviewed and approved by Supply Chain.

Review & Approve Change Controls
135 products @ 10 minutes per change control
22.5 Hours

Artwork Approval
All changes to artwork must be reviewed and approved by Supply Chain in line with company SOPs.

Review & Approve all labels and artwork
680 pieces of artwork @ 0.5 hour per artwork
340 Hours
Regulatory Impact Statement: General Requirements for Labels for Medicines

SAP Codes

Generation of new SAP codes are initiated by Supply Chain.

Initiation of process for SAP code change (involves filling out and routing of forms) for each product

135 forms @ 1 hour per form

SAP code creation for every SKU – involves liaising with Asia Pacific Regional Supply Chain team

210 codes @ 4 hours each code

135 Hours

840 Hours

975 Hours

Communications

Supply Chain is responsible for liaising with the manufacturer to ensure the label changes are implemented at the manufacturing sites.

Liaising with manufacturers

135 products @ 2 hours each

270 Hours

Project Time

It is difficult to estimate the total time required for project management of the changes.

An additional 15% is being allowed to facilitate the additional unaccounted time.

15% Total hours of Change control, artwork, SAP code changes and communications with manufacturers

241.2 Hours

A total 1848.7 hours will required by the JJP Supply Chain function to implement the proposed changes as outlined in TGO 79.

3.6.4 Summary

The direct and indirect impact to the Supply Chain function at JJP has been assessed based on the implementation of the draft TGO 79. The impact considers requirements from a resource perspective (work hours).

From a resource perspective, it is estimated that a total of 1848.7 hours will be used to implement the changes.

Assuming that 1 work week is 38 hours, this equate to 1 Full time employee for 1 year (48 working weeks).

A senior associate would be required for the work to be completed. Additionally, it is estimated that there would be managerial oversight of the senior associate, potentially accounting for 20% of the manager's time.
From a resource perspective this will cost:

48 weeks @ $3388 per week – equates to $162,624

20% managers time: 9.6 weeks @ $3809 per week – equates to $36,567

Total Resource cost – $199,190.

The total resource impact for the Supply Chain function at JJP equates to $199,190.

3.7 Sales & Trade Marketing

3.7.1 Function

The Sales and Trade Marketing function works closely with the Brand Marketing function to ensure the company’s product are marketed and sold to target consumers. The function also liaises with customers to solve any problems that might cause the company to lose customers.

The Sales and Trade Marketing function will need to ensure the customers are aware of the implications associated with the changes proposed in the TGO 79 eg changes to product labelling, Universal Buying Forms (UBF) and point of sale advertising.

3.7.2 Assumptions

In the JJP portfolio there are 28 brands that will be impacted by the proposed changes. Of these 28 brands, it is assumed that there are 9 keys brands. The assumptions are that:

1. The strategic focus will remain on the 9 key brands and does not increase.
2. The 9 key brands are supported with in-store advertising.
3. The times estimated are an average. It is acknowledged that some activities will be shorter than stated. Equally some activities may take longer than quoted.
4. Universal Buying Forms (UBF) will need to be updated as a result of new SAP codes.
5. Any advertising that is updated as a result of the packaging changes are for pack shot changes only. The cost assessment does not include having to redesign brand imagery to ensure compliance with the proposed changes under the draft TGO 79.
6. The costs to dispatch advertising material in New Zealand have not been included.
7. The risk of retailers not accepting 2 different packs (for the same product) on shelves has not been included.
3.7.3 Impact

3.7.3.1 Resource (People) Impact Assessment

Universal Buying Form

Sales and Trade Marketing function is responsible for initiating the process of updating Universal Buying Forms (UBF). The UBF contains all the relevant data required by retailers / wholesalers.

Initiation of process for UBF change (involves filling out and routing of forms)

210 SKU @ 1 hour per SKU

210 Hours

Revising UBFs in internal systems

210 SKU @ 0.5 hours per SKU

Update UBFs for retailers

210 SKU @ 0.5 hours per SKU

420 Hours

Communications

JJP supplies products to 5200 pharmacy outlets nationally. The Sales and Trade Marketing function will be required to communicate with the individual stores to ensure they are aware of the upcoming changes and implications to JJP and the stores as a result of the proposed TGO 79.

Note: Communications to grocery retailers / wholesalers have not been included in this assessment.

Communications to individual stores

5200 stores @ 15 minutes each

1300 Hours

Project Time

It is difficult to estimate the total time required for project management of the changes. An additional 15% is being allowed to facilitate the additional unaccounted time.

15% Total hours of universal buying form and communications

258 Hours

A total 1978 hours will required by marketing to facilitate the proposed changes as outlined in TGO 79.
3.7.3.2 Cost Assessment

Changing Advertising

Most pieces of advertising include pack shots of the product. With a change to the pack designs, all advertising that includes pack shots will need to change to ensure pack shots displayed in the advertisement are consistent with the product available at retail.

Assumptions made are that 9 brands out of 28 are supported with advertising in store. Examples include but are not limited to posters, header cards, pharmacy bins, counter units, wobblers. On average the cost spent on point of sales advertising is $60,000.

Updating out of point of sales material

9 brands @ $60,000 per brand

Digital pack shots will also need to be updated to ensure digital pack shots displayed internally and externally are consistent with the product available at retail.

Updating of digital library

210 SKUs @ $190 per SKU

$54,000

$39,900

$579,900

It is estimated that there will be a financial impact in the vicinity of $579,900 to the Sales and Trade Marketing function to update point of sales advertising material and digital pack shots once the changes proposed as outlined in the draft TGO 79 are implemented.

3.7.4 Summary

The direct and indirect impact to the Sales and Trade Marketing function at JJP has been assessed based on the implementation of the draft TGO 79. The impact considers requirements from a resource perspective (work hours) and from a financial perspective.

From a financial perspective, it is estimated that the impact the Sales and Trade Marketing function will be in the vicinity of $579,900 (exclusive of resource).

From a resource perspective, it is estimated that a total of 1978 hours will be used to implement the changes. Assuming that 1 work week is 38 hours, this equates to 1 Full time employee for 52 working weeks.

A senior associate would be required for the work to be completed. Additionally, it is estimated that there would be managerial oversight of the senior associate, potentially accounting for 20% of the manager’s time.
From a resource perspective this will cost:

52 weeks  @  $3388 per week  -  equates to  $176,176

20% managers time:  10.4 weeks  @  $3809 per week  -  equates to  $39,614

Total Resource cost -  $215,790.

A combined total for resource and direct financial impact for the Sales and Trade Marketing function at JJP equates to  $795,690.

3.8  Consumer Care/Call Centre

3.8.1  Function

JJP employees a team of 7 full time employees to support the consumer care centre (CCC).

This team manages the 1800 number that is on all packs of JJP products, responds to website and email enquiries and manages the monitoring of the social media for the JJP brands. There is a comprehensive database of the JJP products, which includes copies of artwork and Consumer Product Information Forms (CPIF) that the CCC team rely upon to respond to comments and queries from consumers.

With the change in labels from the proposed TGO 79, for every impacted product, all corresponding information in the databases will need to be updated.

3.8.2  Assumptions

In determining the impact to the CCC function, the following assumptions will be made:

1. The times estimated are an average. It is acknowledged that some activities will be shorter than stated. Equally some activities may take longer than quoted.

3.8.3  Impact

CCC Database

Every single artwork charge will require database maintenance - uploading of CPIF, removal of existing approved artwork and uploading of new artwork.

Removal of exiting artwork from the CCC database

220 SKU @ 10 minutes each SKU

Uploading new artwork into the CCC database

220 SKU @ 10 minutes each SKU

Processing and uploading revised CPIFs into the CCC database

135 products @ 0.5 hours per product

Obtaining and replacing physical reference stock used by CCC

135 products @ 15 minutes per product

36.6 hours

36.6 hours

67.5 hours

33.75 hours
Training will be required to ensure the CCC team is familiar with the changes made to each product and how they will respond to consumers who have questions relating to the label changes.

Familiarization of products: 135 products @ 45 minutes per product = 101.25 Hours

Customer Calls: With every major label change, the CCC team receives a number of phone calls and written communications (excluding social media) regarding consumer confusion. With the changes proposed in TGO 79, it is anticipated that the CCC team will have a significant increase in phone calls and written communication. On average, it takes the CCC function ten minutes to process each communication. Since January 2014, the CCC team has received 3443 calls and 1045 written communications relating to OTC products. As the percentage (%), increase for consumer communications is uncertain, a resource impact has not been provided. Based on experience, there is a potential 50% increase in phone calls and written communications received.

Undefined Project Time: It is difficult to estimate the total time required for project management of the changes. An additional 15% is being allowed to facilitate the additional unaccounted time. 15% Total hours of CCC database and training = 41.35 Hours

A minimum of 275.7 hours will be required by CCC to facilitate the proposed changes as outlined in TGO 79.

3.8.4 Summary: The direct and indirect impact to the CCC function at JJP has been assessed based on the implementation of the draft TGO 79. The impact considers requirements from a resource perspective (work hours).
From a resource perspective, it is estimated that a total of 275.7 hours will be used to implement the changes. Assuming that 1 work week is 38 hours, this equates to 11 weeks. A senior associate would be required for the work to be completed. Additionally, it is estimated that there would be managerial oversight of the senior associate, potentially accounting for 20% of the manager’s time.

From a resource perspective this will cost: 

- 7.3 weeks @ $3388 per week – equates to $24,732
- 20% managers time: 1.5 weeks @ $3809 per week – equates to $5,527

Total Resource cost – $30,259.

The total resource impact for the CCC function at JJP equates to $30,259.

3.9 Manufacturers

3.9.1 Function

JJP uses manufacturers across the world to manufacture products supplied to the Australian market. The change that has been proposed under the draft TGO 79 is likely to have a significant impact to the cost of production. All costs incurred by the manufacturer as a result of the label changes (e.g. new printing plates and resource cost) will be charged back to JJP.

3.9.2 Assumptions

In determining the impact for the manufacturers used by JJP, the following assumptions will be made:

1. Equipment and packaging material changes are not impacted by the changes proposed by the TGA.
2. Manufacturer costs from a particular region have been taken from an average of a few manufacturers within that region.
3. The costs associated with manufacturing do not increase.
4. Costs have been based on AU$
5. There are a total of 680 pieces of artwork to be altered as a direct or indirect result of the proposed labelling order. Of the 680 pieces of artwork, 280 pieces account for the SRPs and shippers.
6. All pieces of artwork changes will require new printing plates at the manufacturing sites.
7. The cost for writing off unused raw materials (packaging material) has not been included in this section.

3.9.3 Impact Products Sourced From US

21 products (a total of 22 SKUs) sourced from US manufacturers. A total of 22 shippers, 10 cartons and 26 bottle/can labels will need to be revised as a result of TGO 79. New printing plates will be required for every label.

- Printing plates for shippers: 22 @ $1,500 per shipper = $33,000
- Printing plates for bottle/can labels: 26 @ $5,000 per label = $130,000
- Printing plates for carton labels: 10 @ $3,500 per label = $35,000
- Project management per product: 21 @ $5,000 per product = $105,000

Total: $303,000

Products Sourced From Asia/Middle East/Latin America

11 products (a total of 20 SKUs) sourced from Asian, Middle East or Latin American manufacturers. A total of 20 shippers, 10 SRPs and 41 bottle/can labels will need to be revised as a result of TGO 79. New printing plates will be required for every label.

- Printing plates for shippers: 30 @ $300 per shipper/SRP = $9,000
- Printing plates for bottle/can labels: 41 @ $1,000 per label = $41,000
- Project management per product: 11 @ $1,000 per product = $11,000

Total: $61,000

Products Sourced From Australia

34 products (a total of 56 SKUs) sourced from Australian manufacturers. A total of 56 shippers, 24 SRPs, 13 foil, 3 printed can/tube, 63 carton labels and 31 bottle labels will need to be revised as a result of TGO 79. New printing plates will be required for every label.

- Printing plates for shippers: 56 @ $300 per shipper/SRP = $16,800
- Printing plates for bottle/can labels: 63 @ $1,000 per label = $63,000
- Printing plates for carton labels: 31 @ $3,000 per label = $93,000
- Project management per product: 34 @ $1,000 per product = $34,000

Total: $210,800
Products Sourced From Europe
52 products (a total of 96 SKUs) sourced from European manufacturers. A total of 96 shippers, 26 SRPs, 27 foil, 9 printed can/tubes, 106 carton labels and 36 bottle labels will need to be revised as a result of TGO 79. New printing plates will be required for every label.

Printing plates for shippers
96 @ $1,200 per shipper

Printing plates for SRPs
26 @ $1,200 per SRP

Printing plates for foils
27 @ $1,500 per foil

Printing plates for printed can/tubes
9 @ $5,000 per can/tube

Printing plates for carton labels
106 @ $3,000 per label

Printing plates for bottle labels
36 @ $1,600 per label

Project management per product (includes costs for changes in documentation/systems and labour costs to implement the changes)
52 @ $5,000 per label

Total Cost:
$115,200
$31,200
$40,500
$45,000
$275,600
$57,600
$260,000
$825,100

Products Sourced From South Africa
17 products (a total of 20 SKUs) sourced from South African manufacturers. A total of 20 shippers, 6 SRPs, 12 foil and 16 carton labels will need to be revised as a result of TGO 79. New printing plates will be required for every label.

Printing plates for shippers
20 @ $1,200 per shipper

Printing plates for SRPs
6 @ $1,200 per SRP

Printing plates for foils
12 @ $1,500 per foil

Printing plates for printed can/tubes
16 @ $5,000 per can/tube

Printing plates for carton labels
16 @ $3,000 per label

Project management per product (includes costs for changes in documentation/systems and labour costs to implement the changes)
17 @ $5,000 per label

Total Cost:
$24,000
$7,200
$18,000
$80,000
$48,000
$85,000
$170,000
$502,700
3.9.4 Summary

The direct cost to JJP has been assessed for the proposed changes to the labelling order. This impact is purely financial as all manufacturing is performed outside of JJP. The estimated financial impact for JJP from a manufacturing cost equates to $1,878,500.

3.10 Project Management

3.10.1 Function

The project management function is responsible for ensuring the cross functional teams complete their tasks so that a project is completed on time and within budget. As the changes proposed under the draft 79 will impact 135 products, a project manager will be needed to oversee the project. The project manager will also be responsible for organizing and facilitating team meetings as well as following up with the different functions to ensure the project is on track and that the label changes have been implemented.

3.10.2 Assumptions

In determining the impact the following assumptions will be made.

1. The times estimated are an average. It is acknowledged that some activities will be shorter than stated. Equally some activities may take longer than quoted.
2. As all products are trans-Tasman, the project manager will also ensure the medicines with new labels have been transitioned into the New Zealand market.

3.10.3 Impact
Overseeing Project Team

The Project Manager is responsible for ensuring the project team has implemented the changes proposed in the TGO 79. The core team involved in the artwork change will comprise of Supply Chain, Quality Assurance, Technical Services, and Regulatory Affairs functions.

The resource required from the Project Manager has been based on the average of the resource required by the Supply Chain, Quality Assurance, Technical Services, and Regulatory Affairs functions.

48 weeks

3.10.4 Summary

The direct and indirect impact to the Project Management function at JJP has been assessed based on the implementation of the draft TGO 79. The impact considers requirements from a resource perspective (weeks).

From a resource perspective, it is estimated that a total of 48 weeks will be used to implement the changes. This timeframe is based on the average resource needed by the cross-functional team (Supply Chain, Quality Assurance, Technical Services, and Regulatory Affairs) to implement the label changes.

Given the complexity of the project, a project manager with the experience equivalent to a manager will be required. The resource cost has therefore been calculated based on the wage of a manager.

From a resource perspective this will cost:

48 weeks @ $3809 per week - equates to $182,832.

The total resource impact for the Project Management function at JJP equates to $182,832.
3.11 Finance

3.11.1 Function

The Finance function is responsible for organising the financial and accounting affairs. The Finance function will be required to assess the financial impact to each individual product affected by the proposed changes in the draft of TGO 79.

3.11.2 Assumptions

In determining the impact to the Finance function, the following assumptions will be made:

1. The times estimated are an average. It is acknowledged that some activities will be shorter than stated. Equally some activities may take longer than quoted.

3.11.3 Impact

Financial Impact

Every product impacted by the proposed TGO 79 will need to be assessed from a financial perspective.

Financial assessment

135 products @ 2 hours per product

270 Hours

SAP Codes

Finance is involved in the process for SAP code change.

Review, provide input and approve SAP code change for each product

135 codes @ 1 hour per SAP code

135 Hours

Project Time

It is difficult to estimate the total time required for project management of the changes. An additional 15% is being allowed to facilitate the additional unaccounted time.

15% Total hours of financial impact and SAP codes

60.75 Hours

A total of 465.75 hours will be required by Finance to facilitate the proposed changes as outlined in TGO 79.
3.11.4 Summary

The direct and indirect impact to the Finance function at JJP has been assessed based on the implementation of the draft TGO 79. The impact considers requirements from a resource perspective (work hours).

From a resource perspective, it is estimated that a total of 405 hours will be used to implement the changes. Assuming that 1 work week is 38 hours, this equate to 11 weeks.

A senior associate would be required for the work to be completed. Additionally, it is estimated that there would be managerial oversight of the senior associate, potentially accounting for 20% of the manager's time.

From a resource perspective this will cost:

11 weeks @ $3388 per week - equates to $37,268

20% managers time: 2 weeks @ $3809 per week - equates to $8,380

Total Resource cost - $45,648.

The total resource impact for the Finance function at JJP equates to $45,648.

3.12 Summary of Cross Functional Impact Analysis

The combined total for resource and direct financial impact to the different JJP functions, to implement the draft TGO 79 has been assessed.

Brand Marketing - $1,265,691
Graphic Artist and Design Consultant - $452,800
Regulatory Affairs - $993,329
Technical Services - $128,644
Quality Assurance - $173,292
Supply Chain - $199,190
Sales and Trade Marketing - $795,690
Consumer Care/Call Centre - $30,259
Manufacturers - $1,878,500
Project Management - $182,832
Finance - $45,648

Total - $6,146,875

To account for any unaccounted costs (includes but is not limited to price increases, write-off costs of unused raw materials and additional resource costs) an additional 20% has been applied to the total financial impact as a contingency plan.

The total financial impact to Johnson & Johnson Pacific equates to $7,376,250.
4 Comments on TGA’s Regulatory Impact Statement

JJP is supportive of any initiative that embraces the principles of quality use of medicines and will result in the safer use of medicines. However, there is a distinct lack of evidence that the proposed changes will result in better health outcomes and reduced consumer confusion. The RIS outlines the literature in regard to errors in dosing and considerations that have been raised in the literature on the possible contribution of labels. Prescription medicines and OTC medicines are considered together. JJP believes that the evidence provided is insufficient to demonstrate that the label changes required by the TGO 79 will achieve the objective to reduce the risk of the safety issues for the use of OTC medicines in Australia. On review of the RIS we have the following comments on the literature review concerning patient risk and harm:

- The evidence presented around medication errors concern in-hospital errors or prescription medicines (RIS References 5, 6, 7, 8, 9, 10, 12).

- RIS References 13, 14, 15, 16, 17, 18 (same as 15) used to support the conclusion “poorly designed labels are a significant contributing factor to medication errors”, are US studies. These reports provide useful information on difficulties consumers may experience with US medicine labels however, this information should be considered in the context of the Australian environment versus the US environment where the level of healthcare professional intervention in supply of medicines is very different to the multi-level Australian classification model which provides for consultation with a healthcare professional and where a number of OTC companies have already adopted performance-based label formats tested with Australian consumers.

- RIS References 13, 14, 15, 16, 17, 18 also demonstrate that there are recognised shortcomings in the US Drug Facts Box on which the proposed Medicines Information Panel is based. Thus it is questionable as to whether the adoption of a Medicines Information Panel based on the US Drug Facts Box would be an advancement of OTC medicine labelling in Australia.

- RIS Reference 11 supports outcomes-based standards for labelling. “This outcomes-based approach to regulation does not dictate label content, appearance or design, but rather outlines what information a consumer must be able to readily and easily extract from the label. Outcomes-based standards are governed by an industry code of practice for non-prescription medicines”. This in our view is the optimal approach for labelling OTC medicines. The TGO 79 is not an outcomes-based approach but rather a prescriptive one-size fits-all approach.

- The discussion omits the current use in Australia of performance-based OTC label formats tested with Australian consumers. JJP believes that prescription medicines and non-prescription medicine labelling should be considered separately in a risk based approach. For non-prescription medicines the requirements should reflect Australian performance based testing in the Australian setting.
As the changes proposed in the draft TGO 79 will have a profound impact to the industry, JJP strongly encourages the TGA to consider undertaking some consumer research, using validated methods to ensure the proposed changes to the legislation will have the desired effect and will not result in a retrograde step.

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. However, based on our business impact assessment, it can be seen that the TGO 79 will cost JJP an estimated $7.3 million alone. We do not believe the assumptions made in the RIS are not sufficiently comprehensive and are not reflective of the OTC business as a whole.

We understand that the assumptions made in the RIS were based on the average figures provided by an independent survey in 2014 of 9 companies covering prescription, OTC and complementary medicines. This is clearly an inadequate sample size on which to base cost estimates for decision making purposes given the huge variation in size and culture of businesses across the each medicine sector and between the three sectors (Prescription, OTC and Complementary) and the huge potential impacts of the proposed new Order.

As detailed in Section 3 of this document, label changes and control of the label changes into production and distribution involve many internal and external personnel. The wage rate assumed by the TGA is $42 per hour which is less than half the cost of the industry standard salary ($89.15 per hour). The TGA has also assumed that the estimated pre-production costs for ‘minor and ‘medium’ level label changes, range from $900 to $1937. As seen in ‘Section 3.9 Manufacturers’, the cost of producing 680 labels from a manufacturers perspective alone will cost JJP an estimated $1,878,500. The estimated cost to obtain new printing plates at the manufacturing sites alone equates to approximately $2762 per label. The pre-production cost per label is significantly higher if the cost impact to the different functions of the business is considered.

Additionally, in our business impact assessment, there have been many additional assumptions which do not appear to have been taken into consideration in arriving at the TGA’s RIS cost assessment. Examples include but are not limited application costs to Medsafe for trans-Tasman products, impact to the different functions within a company, changes required to advertising that includes pack shots and the additional complexity incurred in implementing the proposed changes across a number of different manufacturing sites in several different countries.

In summary, we consider that the information provided in the RIS is not sufficient to demonstrate that the label changes required by the TGO 79 will achieve the objective to reduce the risk of the safety issues for the use of OTC medicines in Australia or that current OTC medicine labels generally are a safety issue.

Given the consumer safety is at stake and the huge cost impact that the TGO 79 will have on industry it is beholden upon government to conduct local research into consumer medicine label comprehensibility before implementing any changes, and to be able to measure the improvement in safety brought about by changes to labelling law.
Overview
This document includes Johnson & Johnson Pacific’s comments and proposals in response to the draft TGO 79.

Attachments are included at the end of the document. Bookmarks have also been created to allow easier navigation between the attachments throughout the document.

Note:
Where text has been deleted, this has been indicated with a red font and a strike through the text. Where text has been added, this has been indicated with a blue font and the text has been underlined.
<table>
<thead>
<tr>
<th>Line</th>
<th>Actual Text</th>
<th>Comments</th>
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<tbody>
<tr>
<td>9-11</td>
<td>(1) Other than for the purposes of section 4(3), REVOKE, on and from &lt;&lt;1 January 2018 - tbc&gt;&gt;, Therapeutic Goods Order No. 69 General requirements for labels for medicines made on 27th August 2001, and as amended; and</td>
<td>PROPOSAL</td>
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<td></td>
<td>The five year transitional period is appropriate to:</td>
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<td></td>
<td>• Allow for new labelling dimensions, packaging types and pack dimensions to be developed for current products that would not be able to meet the requirements of the new labelling order.</td>
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<td></td>
<td>• Spread the financial impact to businesses and reduce the likelihood of write off costs.</td>
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<td></td>
<td>Additionally, the TGA has set precedence by giving a five year implementation period to ensure compliance to the ‘Therapeutic Goods (Medical Devices) Regulations 2002’ when it was introduced.</td>
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<tr>
<td>116</td>
<td>This Order commences on &lt;&lt;1 January 2015 – tbc &gt;&gt;.</td>
<td>Consideration as to whether this date is realistic needs to be given since the consultation closed on the 5th of November 2014. Additionally, budgets for the 2015 business year for multinational companies are typically set no later than June of 2014. If this order is implemented on 1st Jan 2015, this will have significant budgetary implications for the industry. Companies would potentially have to wait till 2016 before resource and budget can be invested into the transitioning of new artwork to meet the requirements of TGO 79, which would mean a reduced available implementation time for the industry.</td>
</tr>
<tr>
<td>121-132</td>
<td>(1) On or before &lt;&lt;31 December 2017 – tbc &gt;&gt; each medicine to which this Order applies must comply with either: (a) the requirements specified in this Order, or (b) the requirements specified in Therapeutic Goods Order No 69 General requirements for labels for medicines.</td>
<td>PROPOSAL</td>
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<td></td>
<td>(2) On and from &lt;&lt;1 January 2018 – tbc &gt;&gt; each medicine to which this</td>
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Order applies must comply with the requirements specified in this Order.

(3) Notwithstanding (1) and (2), medicines imported into or manufactured in Australia before <<1 January 2018 – tbc>> but supplied by a person other than the sponsor after that date must comply with Therapeutic Goods Order No 69 General requirements for labels for medicines (TGO 69), if at the time of their release for supply they complied with TGO 69 by reason of (1) above.

<table>
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<tr>
<th>177</th>
<th>Interpretation</th>
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<tr>
<td>It is noted that the draft TGO 79 does not include a definition of a sunscreen. The definition from the Australian Standard is: “4.16 Sunscreen products Products containing any component able to absorb, reflect or scatter UV rays, which are intended to be placed in contact with human skin. [ISO 24444:2010]”</td>
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<tr>
<th>222-224</th>
<th>delivered dose means, in relation to:</th>
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<tr>
<td>(a) pressurised metered dose preparations for inhalation - the dose delivered from the inhaler to the patient in a single actuation or delivery; and</td>
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<tr>
<td>(b) powders for inhalation - the dose delivered from the inhaler in a single delivery;</td>
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<tr>
<td>It should be noted that there are additional delivered dosed medicines that have not been captured. There are pressurised metered dose preparations that are not inhaled (eg Nicotine mouth sprays) and metered dosed medicines that are inhaled and not pressurised (eg Oxymetazoline nasal sprays).</td>
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<tr>
<th>235</th>
<th>diluent means a liquid used for reconstitution or dilution;</th>
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<tbody>
<tr>
<td>PROPOSAL</td>
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<tr>
<td>The definition of diluent should be moved before directions for use to ensure the words in the definitions list remain in alphabetical order.</td>
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<td>236-239</td>
<td><strong>durable</strong>, in relation to a <strong>label</strong>, means that the <strong>label</strong> will not before the <strong>expiry date</strong>, under normal storage conditions deteriorate to the extent of becoming illegible, or become detached from the <strong>container</strong>, packaging or pack, due to the influence of any one or more of the following:</td>
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<tr>
<td>257-259</td>
<td><strong>external</strong>, in relation to the use of a <strong>medicine</strong>, means application in the ears, eyes or nose or to a body surface other than in the mouth, rectum, vagina, urethra or other body orifice;</td>
</tr>
</tbody>
</table>
| 260-263 | **health professional** includes the following:  
(a) a health practitioner of any kind registered under a law of a State or Territory that provides for the registration of health practitioners of that kind; and  
(b) a biomedical engineer, prosthetist or rehabilitation engineer; | **PROPOSAL** | It is proposed to change the definition of ‘health professional’ so that it is aligned with the Therapeutic Goods Act. |
| 296-297 | **label** means a display of printed information upon, or affixed to, the **container**, any **intermediate packaging** and any **primary pack** containing the **medicine**; | **PROPOSAL** | It is noted that the word ‘securely’ that is currently used in the TGO 69 definition of ‘Label’ has not been included in the definition of ‘Label’ in TGO 79 without any explanation as to why the word has been removed. Additionally, to ensure a label meets the requirements of subsection 7(3)(a) ie the label is durable, the label would need to be securely affixed to the container. |
**PROPOSAL**
To be consistent with the current requirements of TGO 69, the TGO 79 should ensure that at a minimum, the name and address of the sponsor/supplier should be provided. The inclusion of an email address or telephone number should be optional.

In the case that a telephone number or an email is required, this should only be provided if space permits.

**PROPOSAL**
It is proposed that lines 321-324 be changed to:

sufficient information about the **sponsor** or supplier, **whether by reason of the inclusion of this being** the sponsor’s or supplier’s street address of its registered place of business in Australia (not being a post office address), an email address or a telephone number, to allow it to be identified so as to facilitate public contact on matters of complaint, use or general enquiry;
**name of the dosage form** means:

(a) in relation to a **medicine** that is intended to be, or is, a **listed goods** or **registered goods**, the name of the dosage form as entered, or proposed to be entered, in the **Register** in relation to the **medicine**; and

(b) in relation to a **medicine** that is not entered in the **Register**, the name of the pharmaceutical form of the **medicine**;

In the interest of minimizing consumer confusion, as per TGO 69, the name of the dosage form should be the ‘usual name’ of the pharmaceutical form of the medicine.

As an example, it would be easier for a consumer to understand ‘Oral Liquid’ as opposed to ‘Oral Liquid, Suspension’.

**PROPOSAL**

It is proposed that lines 343-344 be changed to:

(a) in relation to a **medicine** that is intended to be, or is, a **listed goods** or **registered goods**, the **usual** dosage form as entered, or proposed to be entered, in the **Register** in relation to the **medicine**; and

(b) in relation to a **medicine** that is not entered in the **Register**, the **usual** name of the pharmaceutical form of the **medicine**;

**PROPOSAL**

Information for aerosol products (especially if they are non-metered) should be provided, as it is unclear how the quantity should be expressed. It is proposed that the declared quantity of the medicine should include the weight of the propellant.

Additionally, to align with the requirements of the National Trade Measurement Regulations 2009, the measurements for aerosol medicines should be in a unit of mass.

<table>
<thead>
<tr>
<th>339-344</th>
<th>In the interest of minimizing consumer confusion, as per TGO 69, the name of the dosage form should be the ‘usual name’ of the pharmaceutical form of the medicine. As an example, it would be easier for a consumer to understand ‘Oral Liquid’ as opposed to ‘Oral Liquid, Suspension’. <strong>PROPOSAL</strong> It is proposed that lines 343-344 be changed to: (a) in relation to a <strong>medicine</strong> that is intended to be, or is, a <strong>listed goods</strong> or <strong>registered goods</strong>, the <strong>usual</strong> dosage form as entered, or proposed to be entered, in the <strong>Register</strong> in relation to the <strong>medicine</strong>; and (b) in relation to a <strong>medicine</strong> that is not entered in the <strong>Register</strong>, the <strong>usual</strong> name of the pharmaceutical form of the <strong>medicine</strong>;</th>
</tr>
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<tbody>
<tr>
<td>382-399</td>
<td>(b) where the <strong>medicine</strong> is: (i) a solid or semi-solid, other than a <strong>biological medicine</strong> or a <strong>medicine</strong> for injection - the <strong>nominal weight</strong> of the solid or semi-solid in the <strong>container</strong>; (ii) a liquid, other than a <strong>biological medicine</strong> - the <strong>nominal volume</strong> of the liquid in the <strong>container</strong>; (iii) a pressurised metered-dose preparation or dry powder inhaler - the stated number of deliverable doses in the <strong>container</strong>; (iv) a non-pressurised metered dose preparation - the minimum number of deliverable doses in the <strong>container</strong>; (v) a solid <strong>biological medicine</strong> - the <strong>nominal weight</strong>, number of doses or potency units in the <strong>container</strong>; (vi) a liquid <strong>biological medicine</strong> - the <strong>nominal volume</strong> of liquid in the <strong>container</strong> and (A) the <strong>nominal weight</strong>, total number of doses or potency</td>
</tr>
</tbody>
</table>

**PROPOSAL** Information for aerosol products (especially if they are non-metered) should be provided, as it is unclear how the quantity should be expressed. It is proposed that the declared quantity of the medicine should include the weight of the propellant.

Additionally, to align with the requirements of the National Trade Measurement Regulations 2009, the measurements for aerosol medicines should be in a unit of mass.
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<tr>
<td>407-408</td>
<td><strong>small container</strong> means a <strong>container</strong> which has a <strong>capacity</strong> less than or equal to 25 millilitres that is not a <strong>very small container</strong>;</td>
<td>It is very unlikely for medicines to be filled to the brim of a bottle. A bottle that has a capacity of 25 mL would most likely contain 20 mL of product. The definition of a small container should be determined by the volume of the medicine rather than the capacity of the container. Note: The appropriateness of 25 mL being the cut off for a container to be classified as a ‘small container’ and the inclusion of other smaller packages eg cartons to be considered as ‘small containers’ is discussed further below. <strong>PROPOSAL</strong> It is proposed that lines 407-408 be changed to: <strong>small container</strong> means a <strong>container which has a capacity contains</strong> less than or equal to 25 <strong>xx</strong> millilitres of medicine that is not a <strong>very small container</strong>;</td>
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<tr>
<td>440</td>
<td>(a) be clearly visible and not be obscured; and Products that are enclosed in cartons or backing boards will not be able to meet this requirement as the label on the container will be obscured by the primary pack. <strong>PROPOSAL</strong> It is proposed that the words ‘and not be obscured’ be removed from lines 440 or apply the ‘not to be obscured’ section to primary packs only.</td>
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<tr>
<td>442</td>
<td>(c) be in <strong>durable</strong> and legible characters; and Batch numbers and expiry dates are commonly embossed/debossed onto carton and blister platforms. When the medicine is packaged into a tube, the batch number and expiry date is commonly crimped onto the base of the tube. If embossing, debossing and crimping is no longer allowed,</td>
<td></td>
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</table>
Manufacturers will require capital investment to set up new equipment that will print information such as batch numbers and expiry dates onto the labels.

**PROPOSAL**
The requirements of TGO 79 should ensure the use of embossing, debossing and crimping of information remains acceptable as long as the text and information is clearly visible and legible.

| 443-444 | (d) unless otherwise specified, be displayed in text size of not less than the equivalent of 6 point Arial; and |

**PROPOSAL**
To provide clarification and ensure that other sans serif font can be used, it is proposed to change lines 443-444 to:

unless otherwise specified, be displayed in text size of not less than the equivalent of 6 point Arial in any sans serif font; and

| 445 | (b) be in a colour or colours contrasting strongly with the background; and |

**PROPOSAL**
All information required by this Order is already required to be legible.

As mentioned above, the document should ensure the use of embossing, debossing and crimping remains acceptable as long as the text is information is clearly visible.

**PROPOSAL**
It is proposed to change line 445 to:

be in a colour or colours that are legible. This may be achieved by use of contrasting background contrast strongly with the background; and

| 446 | (c) unless otherwise specified, be in a metric unit of measurement only. |

**PROPOSAL**
The current wording implies that only metric units of measurements are permissible. This will restrict opportunities for sharing packaging components with other markets. The inclusion of a non-metric measure should be allowable, as long as there is the mandatory metric measurement.


It is proposed to change line 446 to:

unless otherwise specified, be in a metric unit of measurement only.

Consideration should be given to small containers that are enclosed in a blister with a backing card eg nasal sprays and refills.

It is noted that in TGO 69, both the labels on container AND the primary pack (if any) would need to meet the ‘General’ label requirements. Based on the draft TGO 79, it is interpreted that the labelling on a container OR a primary pack (but not both) would need to meet the requirements of subsection 8. As it is unclear whether this was the TGA’s intention, clarification should be provided.

It is also noted that in subsection 12(l) the listing number is required to be set out on the label.

Similarly, the registration or listing number should be included in Section 8.

**PROPOSAL**

It is proposed that the following statement (or words to the effect) be included into Section 8:

The listing or registration number, set out on the **label** consistent with the requirements specified in the Regulations.
the name and contact details of the sponsor or supplier of the medicine as at the date of release for supply or, where there was a change in the name or contact details of the sponsor or supplier, whether by reason of a change of supplier or sponsor or otherwise, within the 12 months preceding that date, the name and contact details of the sponsor or supplier immediately prior to that change; and

Consideration for slow moving, seasonal medicines and medicines that only have batches manufactured once a year needs to be given.

PROPOSAL
It is proposed that the timeframe for changing sponsor details should not be defined, on the provision that the ‘receiving sponsor’ has mechanisms in place, such that they can be contacted by consumers, regulators and health care professionals.

Additionally, the implementation should be defined such that the release for supply date refers to the release for supply from the manufacturing site ie the last step of manufacturing.

warning statements, where these are required in relation to a particular medicine or in specified circumstances applying to a particular medicine such as the following:

(i) where the medicine is for external use the required statement is ‘Caution: Not to be Swallowed’, or ‘For External Use Only’, or words to this effect;

As RASML is intended to capture all the necessary warning statements required for a medicine, subsection (k)(i), (ii) and (iii) should not be required.

(ii) where:

(A) the medicine is for oral use; and

Additionally, this section of the draft TGO 79 contradicts RASML. Using Cetirizine as an example, if the medicine was indicated for children, based on the current draft of TGO 79, a pregnancy warning statement would be required on the medicine label since the medicine is classified as Category B1. However, RASML 2 separates adults and children’s warning statements in relation to pregnancy, thus children products would not require a pregnancy warning statement.

PROPOSAL
To ensure that no new warning statements are introduced as a result of TGO 79, it is proposed to change lines 504-546 to:

(k) warning statements, where these are required in relation to a particular medicine or in specified circumstances applying to a particular medicine such as the following:

(i) where the medicine is for external use the required statement is ‘Caution: Not to be Swallowed’, or ‘For External Use Only’, or words to this effect;
the required statement is: ‘If pregnant or likely to become pregnant, consult a pharmacist or a doctor before use’ or words to this effect;

(iii) where:

(A) the medicine is a registered goods for oral use; and

(B) the medicine does not contain a substance included in Schedule 4 or Schedule 8 of the Poisons Standard; and

(C) the medicine contains active ingredient(s) included in category ‘D’ in the document titled ‘Prescribing medicines in pregnancy database’ published on the TGA website as at the date of commencement of this Order; and

(D) the medicine is not subject to other specific warning statements(s) relating to use during pregnancy,

the required statement is ‘Do not use this medicine if pregnant or likely to become pregnant’ or words to this effect; and

(ii) where:

the medicine is for oral use; and

the medicine does not contain a substance included in Schedule 4 or Schedule 8 of the Poisons Standard; and

the medicine contains active ingredient(s) included in category ‘B’ (including ‘B1’, ‘B2’, ‘B3’) or category ‘C’ in the document titled ‘Prescribing medicines in pregnancy database’ published on the TGA website as on the date of commencement of this Order; and

the medicine is not subject to other specific warning statement(s) relating to use during pregnancy,

the required statement is: ‘If pregnant or likely to become pregnant, consult a pharmacist or a doctor before use’ or words to this effect;

(iii) where:

the medicine is a registered goods for oral use; and

the medicine does not contain a substance included in Schedule 4 or Schedule 8 of the Poisons Standard; and

the medicine contains active ingredient(s) included in category ‘D’ in the document titled ‘Prescribing medicines in pregnancy database’ published on the TGA website as at the date of commencement of this Order; and

the medicine is not subject to other specific warning statement(s) relating to use during pregnancy,

the required statement is: ‘Do not use this medicine if pregnant or likely to become pregnant’ or words to this effect; and

Where new warning statements have been introduced in TGO 79 and are necessary, these statements should be included into RASML instead. This will minimize the number of documents sponsors/manufacturer will need to refer to when they are looking for the relevant warning statements for medicines.

512-513 (B) the medicine does not contain a substance included in Schedule 4 or Schedule 8 of the Poisons Standard; and

There are substances such as Paracetamol and Ibuprofen that are included in Schedule 4, but in some instances are exempt from scheduling, included in Schedule 2 or included in Schedule 3 of the
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<tr>
<td>524-525</td>
<td>(B) the <strong>medicine</strong> does not contain a substance included in Schedule 4 or Schedule 8 of the <strong>Poisons Standard</strong>; and</td>
<td>There are substances such as Paracetamol and Ibuprofen that are included in Schedule 4, but in some instances are exempt from scheduling, included in Schedule 2 or included in Schedule 3 of the Poisons Standard.</td>
</tr>
<tr>
<td>534-537</td>
<td>(i) <strong>directions for use</strong> of the <strong>medicine</strong> except where:</td>
<td>There are substances such as Paracetamol and Ibuprofen that are included in Schedule 4, but in some instances are exempt from scheduling, included in Schedule 2 or included in Schedule 3 of the Poisons Standard.</td>
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<td></td>
<td>(i) the <strong>medicine</strong> contains a substance that is included in Schedule 4 or Schedule 8 of the <strong>Poisons Standard</strong>, or is a human blood product included in Appendix A of the <strong>Poisons Standard</strong>; or</td>
<td><strong>PROPOSAL</strong> To provide further clarity and to ensure that the proposed statement applies to products classified as Schedule 4 or Schedule 8, it is proposed that lines 524-525 be changed to:</td>
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<td></td>
<td></td>
<td>the <strong>medicine</strong> does not contain a substance included in <strong>is not classified as</strong> Schedule 4 or Schedule 8 of the <strong>Poisons Standard</strong>; and</td>
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<td></td>
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<td><strong>PROPOSAL</strong> To provide further clarity and to ensure that the proposed statement applies to products classified as Schedule 4 or Schedule 8, it is proposed that lines 534-537 be changed to:</td>
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<td></td>
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<td>the <strong>medicine</strong> contains a substance that is included in <strong>is classified as</strong> Schedule 4 or Schedule 8 of the <strong>Poisons Standard</strong>; or</td>
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<tr>
<td>547-550</td>
<td>(m) if the <strong>medicine</strong> requires some preparation, such as dissolving, suspending, diluting or reconstituting before use - instructions for its preparation and, where relevant, a statement of the conditions of storage and the maximum period of storage between preparation and use, except where:</td>
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<td><strong>PROPOSAL</strong> To ensure that all preparation methods are accounted for, it is proposed that lines 547-550 be changed to:</td>
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<td>if the <strong>medicine</strong> requires some preparation, such as, <strong>but not limited to</strong>, dissolving, suspending, diluting or reconstituting before use - instructions for its preparation and, where relevant, a statement of the conditions of storage and the maximum period of storage between preparation and use, except where:</td>
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<tr>
<td>560-562</td>
<td>(i) the <strong>medicine</strong> contains a substance that is included in Schedule 4 or Schedule 8 of the <strong>Poisons Standard</strong>, or is a human blood product included in Appendix A of the <strong>Poisons Standard</strong>; or</td>
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<td></td>
<td>There are substances such as Paracetamol and Ibuprofen that are included in Schedule 4, but in some instances are exempt from scheduling, included in Schedule 2 or included in Schedule 3 of the Poisons Standard.</td>
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<td><strong>PROPOSAL</strong> To provide further clarity and to ensure that the proposed statement applies to products classified as Schedule 4 or Schedule 8, it is proposed that lines 560-562 be changed to:</td>
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<td>the <strong>medicine</strong> contains a substance that is included in <strong>is classified as</strong> Schedule 4 or Schedule 8 of the <strong>Poisons Standard</strong>, or is a human blood product included in Appendix A of the <strong>Poisons Standard</strong>; or</td>
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<tr>
<td>578-581</td>
<td>(p) a <strong>machine readable code</strong>, if the <strong>medicine</strong> contains a substance that is included in Schedule 4 or Schedule 8 of the <strong>Poisons Standard</strong>, or is a human blood product included in Appendix A of the <strong>Poisons Standard</strong>, except where the <strong>medicine</strong> is a <strong>starter pack</strong>;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>There are substances such as Paracetamol and Ibuprofen that are included in Schedule 4, but in some instances are exempt from scheduling, included in Schedule 2 or included in Schedule 3 of the Poisons Standard.</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>PROPOSAL</strong> To provide further clarity and to ensure that the proposed statement applies to products classified as Schedule 4 or Schedule 8, it is proposed</td>
<td></td>
</tr>
</tbody>
</table>
that lines 578-581 be changed to:

- **a machine readable code**, if the medicine contains a substance that is included in Schedule 4 or Schedule 8 of the *Poisons Standard*, or is a human blood product included in Appendix A of the *Poisons Standard*, except where the medicine is a **starter pack**;

582-586

(q) a minimum space of 70 x 30 millimetres for the dispensing **label**, if the **medicine** contains a substance that is included in Schedule 4 or Schedule 8 of the *Poisons Standard*, or is a human blood product included in Appendix A of the *Poisons Standard*, unless precluded by the dimensions of the **primary pack**; and

There are substances such as Paracetamol and Ibuprofen that included in Schedule 4 but also, in some instances to be exempt from scheduling, included in Schedule 2 or Schedule 3 of the *Poisons Standard*.

**PROPOSAL**

To provide further clarity and to ensure that the proposed statement applies to products classified as Schedule 4 or Schedule 8, it is proposed that lines 582-586 be changed to:

- a minimum space of 70 x 30 millimetres for the dispensing **label**, if the **medicine** contains a substance that is included in Schedule 4 or Schedule 8 of the *Poisons Standard*, or is a human blood product included in Appendix A of the *Poisons Standard*, unless precluded by the dimensions of the **primary pack**; and

587-588

(r) where the **medicine** is packaged in a **primary pack** that is a carton, that **name of the medicine** on at least three non-opposing sides of the carton.

Based on the document *Comparing TGO 79 with TGO 69 v1.0 August 2014*, this requirement was introduced to ensure that medicines can always be stacked so that the name is visible.

**PROPOSAL**

It is proposed that this requirement be restricted to Prescription medicines, as prescription medicines are more likely to be stacked in a way that the medicine name is not visible. Non-prescription medicines are stacked on shelves so that the main panel (which includes the product name) is facing the consumer.

Additionally, this requirement assumes that the carton consists of 6 sides. Primary pack cartons that have less than 6 sides (e.g., pillow packs) will not be able to meet this requirement.
Refer to Attachment 1 for an example of a pillow pack.

| 607-608 | (b) the name(s) of all **active ingredients** in the **medicine**; and  
|  | (c) the quantity or proportion of all **active ingredients** in the **medicine**; and  
|  | As it is unclear whether the bolded ‘active ingredients’ words in line 697 were intended to refer to ‘active ingredient’ or ‘names of active ingredient’ from the definitions section, clarification should be provided as to whether the ‘therapeutically active component’ names or the ‘Australian Approved Name’ of the ingredient is required on the main label.  
|  | In the case that the TGA’s intention was to include the Australian Approved Name of the active ingredients, the name of the ingredient would include the salt and hydrate name. For all non-prescription products, JJP does not believe the inclusion of the salt or hydrate name on the main label would provide any benefit to the consumer and could potentially cause confusion if different salts or hydrates are used for the same active moiety in different formulations (eg Sodium Ibuprofen Dihydrate vs Ibuprofen Lysine). For a consumer, it would be more important for them to know the active moiety of the ingredient rather than the full ingredient name.  
|  | PROPOSAL  
|  | In the interest of ensuring the main label is simple enough for the consumer to identify the therapeutically active ingredient in the medicine, it is proposed to exclude the salt or hydrate component of the active ingredient name on the main label.  
|  | Examples of current medicine labels from the UK have been provided (Refer to Attachment 2) to show that the MHRA do not require the main label of medicines to include the salt in the active ingredient name and the full name of the ingredient is only provided on the back panel of the carton.  
|  | In our proposal to exclude the salt or hydrate in the active ingredient name, the following points have been considered:
Where the salt or hydrate of the active ingredient needs to be identified, the consumer or health care professional can still locate the full name of the active ingredient in the Medicine Information Panel.

The decision made by the TGA needs to be aligned by MEDSAFE to ensure that trans-Tasman labelling can still be used between the Australian and New Zealand market. If different labels are used for the two countries, the cost of manufacturing will increase. In the case that the medicine is not sustainable for the New Zealand market (from a business perspective), there is the risk that the medicine will be discontinued in New Zealand.

There are medicines such as antacids where the active ingredient is a salt (e.g., Calcium Bicarbonate and Calcium Carbonate). In this scenario; the full active ingredient name should be included on the main label.

As the salt is required to be included in the active ingredient name for prescription medicines, the proposal should only apply to non-prescription medicines.

Where sponsors decide to include the salt name in the active ingredient name, the quantity expressed on the label will be different compared to the quantity of an active ingredient on a medicine which does not include the salt in the active ingredient name (e.g., Phenylephrine Hydrochloride 5mg vs Phenylephrine 4.2mg). This could potentially cause confusion for consumers as they may think the medicine which states ‘Phenylephrine Hydrochloride 5mg’ would have a higher level of active ingredient compared to a medicine labelled ‘Phenylephrine 4.2mg’, even though both products contain the same amount of active ingredient.

Additionally, if the main label stated ‘Phenylephrine 4.2mg’, the Medicine Information panel would state ‘Phenylephrine Hydrochloride 5mg’. This scenario would also cause confusion for the consumers.
In order to prevent these scenarios from happening, it is proposed to exclude the quantity statement of the active ingredient on the main label. In the case where the quantity of the active ingredient needs to be identified, the consumer can still locate this information in the Medicine Information panel.

Lines 607-608 will subsequently be changed to:

(b) the name(s) of all active ingredients in the medicine; and

c) the quantity or proportion of all active ingredients in the medicine; and

Mock up labels have been provided to show how the main label of the primary pack on the medicine would look when:
- the salt of the active ingredient name has been excluded
- different font sizes are used (discussed further below)

Refer to Attachment 3, Attachment 4 and Attachment 5.

Examples of current medicine labels from the UK, Ireland and the US have been provided (Refer to Attachment 6) to show that other jurisdictions do not require the quantity of the active ingredient to be on the main panel.

In our proposal to exclude the quantity statement of the active ingredient on the main label, we have considered how consumers could easily identify medicines which came in different strengths.

We propose that the inclusion of a description relating to the strength of the active ingredient to be required in the product name and that it is prominently displayed on the main label.

Descriptions to be incorporated into the Medicine name could include
words such as ‘DOUBLE STRENGTH’, ‘FORTE’ or ‘EXTRA STRENGTH’ or the use of numbers to highlight the concentration of the active ingredient eg ADVIL 400 DOUBLE STRENGTH CAPLETS Aust R 207376 (contains 400mg Ibuprofen). In the case of TELFAST which comes in strengths of 60mg, 120mg and 180mg of Fexofenadine Hydrochloride, the products would be renamed to TELFAST 60, TELFAST 120 and TELFAST 180 respectively.

**SUMMARY**
In summary, it is proposed:
1. To exclude the salt and hydrate component of the active ingredient name when included on the main label, unless the salt is the active ingredient
2. To exclude the quantity statement of the active ingredient on the main label
3. In the case that the medicine is available in multiple strengths, the inclusion of a description relating to the strength of the active ingredient is required in the product name and that it is prominently displayed on the main label.

(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**

The current wording of lines 627-629 would require the information relating to active ingredient names to be placed immediately after the medicine name which will limit the use of trademarks and impact global brand identity.

Examples of medicine labels from the UK, Ireland, Canada and current TGA approved artwork have been provided to show that even though the medicine name and information relating to the active ingredients have been separated by additional text or graphics, the required information is still clearly visible (refer to **Attachment 7**).

**PROPOSAL**
As the use of additional graphics and/or text can help the consumer to easily identify what the medicine is used for, it is proposed that the use
of text and graphics in between the medicine name and active ingredients should be allowed as long as the information is not obscured, remains legible and is in the same order.

| 630-631 | (4) All text required by this Order to be on the **main label** must be oriented in the same direction. | As mentioned above, the registration number/listing number should be included into the TGO 79. If this proposal is implemented, the registration/listing number should continue to be allowed to be in a different orientation to all other text on the main label. |

**PROPOSAL**
It is proposed to change lines 630-631 to:

All text required by this Order, with the exception of the Registration or Listing number, to be on the **main label** must be oriented in the same direction.

| 637-645 | (6) Subject to (8), if the **medicine** is intended to be, or is, **listed goods**:  
(a) if the **medicine** is a sunscreen preparation - the name of every **active ingredient**, together with the quantity or proportion of every **active ingredient**, and the **name of the dosage form**, may appear on a side panel or side **label** or on a rear panel or rear **label**; or  
(b) if there are four or more **active ingredients** in the **medicine** - the name of every **active ingredient**, together with the quantity or proportion of every **active ingredient**, may appear on a side panel or side **label** or on a rear panel or rear **label** | **PROPOSAL**
To provide further clarification to subsection 9(6), it is proposed to changes lines 637-645 to:

(6) Subject to (8), if the **medicine** is intended to be, or is, **listed goods**:  
(a) if the **medicine** is a sunscreen preparation - the name of every **active ingredient**, together with the quantity or proportion of every **active ingredient**, and the **name of the dosage form**, may appear on a side panel or side **label** or on a rear panel or rear **label**; or  
(b) **listed goods** - if there are four or more **active ingredients** in the **medicine** - the name of every **active ingredient**, together with the quantity or proportion of every **active ingredient**, may appear on a side panel or side **label** or on a rear panel or rear **label** |

| 646-649 | (7) Subject to (8), if the **medicine** is intended to be, or is, **registered goods**:  
(c) the name of the **active ingredient(s)** and the quantity or | Main label artworks have been mocked up to meet the requirements of subsection 9(7). Mock up labels have also been provided to show how the main label of |
the 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; and the primary pack on the medicine would look when:
- different font sizes are used
- the salt of the active ingredient name has been excluded (discussed above)

Refer to Attachment 3, Attachment 4 and Attachment 5.

Although the increase in font size for the active ingredient name and quantity is intended to help the consumer identity the active ingredient in the medicine, as shown in Attachment 3, Attachment 4 and Attachment 5, the increase in font size will potentially make the text more difficult to read.

It should also be noted that for products containing more than two active ingredients, it would be difficult for sponsors/manufacturers to comply with the requirements of subsection 9(7).

In order to meet the 15 point Arial font size, information which may be important for the consumers will need to be removed from the main panel. Product claims and attributes on the main panel are important as they help the consumers to self-select non-prescription medicines. The other option of meeting the 15 point Arial font size requirement would be to increase the packaging dimensions of the product. However, this option would have a significant impact to sponsors and manufacturers as there will be an increase in both manufacturing costs and complexity. Additionally, with the increase in packaging size, pharmacies and grocery channels may not accept the product due to limitations in shelf space. This could potentially result to the product being delisted in retail.

The current requirements of TGO 79 would also require primary packs of ‘small containers’ to include the active ingredient name on the main panel in a font size of 15 point Arial, which will be unachievable for many current OTC products that would be classified as ‘small containers’.
Note: The appropriateness of introducing a large font size for small containers is further discussed below.

**PROPOSAL**

A 10pt font for active ingredient names has been proposed for registered medicines if the salt name and quantity of the active ingredient is not required. We believe this font size would be more easily adaptable to different sized shapes of containers, ensuring that the active ingredient name is prominent and at the same time remain clearly legible.

In the case that the TGA requires the salt and quantity of the active ingredient to be included on the main panel, we believe that an 8pt font would be appropriate.

It is also unclear whether ‘Registered Complementary Medicines’ will need to meet this requirement. Further clarification should be provided.

**PROPOSAL**

It is proposed that a definition for ‘Registered Complementary Medicines’ should be provided in the TGO 79 or in the ‘Guideline for the labelling of Medicines’ to clarify whether Registered Complementary Medicines would be classified as ‘registered goods’ and as a result, required to meet the requirements of subsection 9(7).

<table>
<thead>
<tr>
<th>655-664</th>
<th>(8) If the medicine is intended to be, or is, registered goods and there are four or more active ingredients and:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(a) subsection 10(20) does not apply - the names of every active ingredient, together with the quantity or proportion of every active ingredient, may be included on a side panel or side label or on a rear panel or rear label, displayed in a text size of not less than the equivalent of 12 point Arial in any sans serif font; or</td>
</tr>
<tr>
<td></td>
<td>It is currently unclear how this section would apply to medicines that are composite packs.</td>
</tr>
<tr>
<td></td>
<td>Using an example of a composite pack which contains:</td>
</tr>
<tr>
<td></td>
<td>medicine 1 (4 active ingredients) and medicine 2 (3 active ingredients)</td>
</tr>
<tr>
<td></td>
<td>Both medicines are enclosed in the same blister.</td>
</tr>
</tbody>
</table>
(b) 10(20) applies - the names of every active ingredient, together with the quantity or proportion of every active ingredient, need not be displayed on the main label.

It is unclear whether this composite pack is considered to have 7 active ingredients in total and therefore subsection 9(8) would apply or whether only subsection 9(8) would only apply to medicine 1.

**PROPOSAL**
Further information relating to composite packs should be provided in this section and/or in subsection 10(19) composite packs.

| 889 | (12) Medicine kits | As medicine kits are classified as Listed Goods, the labelling requirements for a Listed Medicine would apply to the medicine kit.

Our interpretation of the label on the package that, together with medicines, constitutes a medicine kit, would not require:

- The name and quantity or proportion of all active ingredients in each of the medicines within the kit to be included on the main panel of the primary pack (assuming the Medicine Kit was packaged in a primary pack).
- The name and quantity or proportion of all active ingredients in each of the medicines within the kit to be included in 15 point Arial.
- A Medicine Information panel.

A statement should be provided in the TGO 79 or in the ‘Guideline for the labelling of Medicines’ document to confirm this.

| 898-900 | (f) a statement of purpose for each medicine within the kit except where a medicine contains a substance that is included in Schedule 4 or Schedule 8 of the Poisons Standard; and | There are substances such as Paracetamol and Ibuprofen that are included in Schedule 4, but in some instances are exempt from scheduling, included in Schedule 2 or included in Schedule 3 of the Poisons Standard.

**PROPOSAL**
To provide further clarity and to ensure that the proposed statement applies to products classified as Schedule 4 or Schedule 8, it is proposed that lines 898-900 be changed to:
<table>
<thead>
<tr>
<th>Page</th>
<th>Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>901-904</td>
<td>(g) <em>directions for use</em> for each <em>medicine</em> within the kit or a statement directing consumers to the directions for use on the <em>label</em> of each <em>medicine</em> within the kit, except where the <em>medicine</em> contains a substance that is included in Schedule 4 or Schedule 8 of the <em>Poisons Standard</em>; and</td>
</tr>
<tr>
<td></td>
<td>There are substances such as Paracetamol and Ibuprofen that are included in Schedule 4, but in some instances are exempt from scheduling, included in Schedule 2 or included in Schedule 3 of the Poisons Standard. <strong>PROPOSAL</strong> To provide further clarity and to ensure that the proposed statement applies to products classified as Schedule 4 or Schedule 8, it is proposed that lines 901-904 be changed to:</td>
</tr>
<tr>
<td></td>
<td><em>directions for use</em> for each <em>medicine</em> within the kit or a statement directing consumers to the directions for use on the <em>label</em> of each <em>medicine</em> within the kit, except where the <em>medicine</em> contains a substance that is included in Schedule 4 or Schedule 8 of the <em>Poisons Standard</em>; and</td>
</tr>
<tr>
<td>933-934</td>
<td>(b) the <em>container</em> is enclosed in a <em>primary pack</em>, the <em>label</em> of which complies with the requirements of this Order,</td>
</tr>
<tr>
<td></td>
<td>As discussed above, the current requirements of TGO 79 would require primary packs of ‘small containers’ to include the active ingredient name on the main panel in a font size of 15 point Arial, however the corresponding primary packs will in most cases match the size of the immediate container and it would be difficult to meet this requirement. Using a current 15mL medicine as an example, a mock up label has been created to meet the current requirements of TGO 79. Mock up labels have also been provided to show how the main label of the primary pack on the medicine would look when:</td>
</tr>
<tr>
<td></td>
<td>- the salt of the active ingredient name has been excluded (as discussed above)</td>
</tr>
<tr>
<td></td>
<td>- different font sizes are used</td>
</tr>
<tr>
<td></td>
<td>Refer to Attachment 8.</td>
</tr>
</tbody>
</table>
**PROPOSAL**

As the font size for the active ingredient name on the container is Arial point 8, it is proposed that where a medicine is a ‘small container’, the active ingredients listed on the corresponding main label of the primary pack should allow for a font size of 8 point Arial.

Currently, the only information printed onto the patch is the ‘Nicorette’ brand name. The printing is achieved by using ‘Tampon printing’ machinery. This is the only information printed onto the patches and the printing process is common and shared across the different markets in the world.

In order to meet the requirements of subsection 10(d), sharing of bulk product would no longer be possible. This would lead to new printing equipment/settings to be setup and as a result, there will be an increase in manufacturing complexity and costs specifically for Australia.

Additionally, it is unclear why transdermal patches will require the information specified in subsection 10(d). In the case of nicotine, where the strength of the active ingredient is unlikely to have a safety implication to the consumer, the inclusion of the strength of the
**PROPOSAL**

As, Nicotine patches can already be identified by the brand name and the inclusion of the strength of the active ingredient will have no added benefit to the consumer or health care professional, it is proposed that transdermal Nicotine Replacement Therapy products be exempt from the requirements of subsection 10(16)(d).

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| 1030-1063 | **(17) Strip, blister and dial dispenser packs**
<table>
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<th></th>
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</thead>
<tbody>
<tr>
<td>(a) Subject to paragraph (b), if:</td>
<td>medicine on the patch would not provide any additional benefits to the consumer and health care professionals.</td>
</tr>
<tr>
<td>(i) a <strong>medicine</strong> consists of individual dosage units such as tablets, capsules, pastilles, cachets, lozenges, pessaries, suppositories or single doses of powder; and</td>
<td>PROPOSAL</td>
</tr>
<tr>
<td>(ii) two or more dosage units are individually enclosed in a strip, blister or <strong>dial dispenser pack</strong> such that the dosage units can only be extracted individually; and</td>
<td>Using an example of a composite pack which contains:</td>
</tr>
<tr>
<td>(iii) the strip, blister or <strong>dial dispenser pack</strong> is enclosed in a <strong>primary pack</strong>, the <strong>label</strong> of which complies with the requirements of this Order,</td>
<td><strong>medicine 1</strong> (4 active ingredients) and <strong>medicine 2</strong> (3 active ingredients)</td>
</tr>
<tr>
<td>then the <strong>label</strong> on the strip, blister or <strong>dial dispenser pack</strong> must comply with sections 8 and 9 except where the following information is set out on that <strong>label</strong>:</td>
<td>Both medicines are enclosed in the same blister.</td>
</tr>
<tr>
<td>(iv) the <strong>name of the medicine</strong>; and</td>
<td>It is unclear whether this composite pack is considered to have 7 active ingredients and therefore subsection10(17)(b) would apply, or whether subsection10(17)(b) would only apply to <strong>medicine 1</strong> and subsection10(17)(a) would still apply to <strong>medicine 2</strong>.</td>
</tr>
<tr>
<td>(iii) the name(s) of all <strong>active ingredients</strong> in the <strong>medicine</strong>; and</td>
<td>If subsection10(17)(a) still applied to <strong>medicine 2</strong>, this could cause confusion for the consumer as they would only see the names and quantities of the active ingredients in <strong>medicine 2</strong> on the blister.</td>
</tr>
<tr>
<td>(vi) the quantity or proportion of all <strong>active ingredients</strong> in the <strong>medicine</strong>; and</td>
<td><strong>PROPOSAL</strong></td>
</tr>
<tr>
<td>(vii) the <strong>batch number</strong> of the <strong>medicine</strong> preceded by the <strong>batch number prefix</strong>; and</td>
<td>Further information relating to composite packs should be provided in this section and/or in subsection 10(19) composite packs.</td>
</tr>
<tr>
<td>(viii) the <strong>expiry date</strong> of the <strong>medicine</strong> preceded by the <strong>expiry date</strong></td>
<td></td>
</tr>
</tbody>
</table>
prefix; and

(x) the name of the sponsor or supplier, or registered trademark that readily identifies the sponsor or supplier of the medicine.

(b) If in relation to a medicine referred to in (a) there are:

(i) four or more active ingredients in the medicine and the medicine is intended to be, or is, registered goods; or

(ii) two or more active ingredients in the medicine and the medicine is intended to be, or is, listed goods,

then the label on the strip, blister or dial dispenser pack must comply with sections 8 and 9 except if there are set out on that label, the following information:

(iii) the name of the medicine; and

(iv) the batch number of the medicine preceded by the batch number prefix;

(v) the expiry date of the medicine preceded by the expiry date prefix; and

(vi) the name of the sponsor or supplier, or registered trademark that readily identifies the sponsor or supplier of the medicine.

1099-1107

(19) Composite packs

(a) The expiry date on the package that, together with medicines, constitutes a composite pack must be the earliest of the expiry dates of the medicines that constitute the composite pack.

(b) The storage conditions on the package that, together with medicines, constitutes a composite pack must be the most restrictive of the storage conditions of the medicines that constitute the composite pack.

Note: The label on the container and primary pack (if any) of each medicine comprising a composite pack must comply with this Order.

Further information relating to the requirements for Composite packs should be provided in this section.

It is unclear how the name and quantity or proportion of every active ingredient in each of the medicines within the composite pack needs to be expressed on the main panel of the primary pack.

Consideration needs to be given the label requirements for composite packs. As composite packs have multiple formulations which can consist of multiple ingredients per formula, it is unlikely that the label could meet the requirements of subsection 9 of the draft TGO 79.
Additionally, as discussed above, in the case that there are 4 or more active ingredients in the composite pack, it is unclear how the requirements of subsection 9(8) would apply.

Using an example of a composite pack which contains:
**medicine 1** (4 active ingredients) and **medicine 2** (3 active ingredients)
Both medicines are enclosed in the same blister.
It is unclear whether this composite pack is considered to have 7 active ingredients in total and therefore subsection 9(8) would apply or whether only subsection 9(8) would only apply to **medicine 1**.

If subsection 9(8) only applied to **medicine 1**, this could cause confusion for the consumer as they would only see the names and quantities of the active ingredients in **medicine 1** on main label of the primary pack.

**Proposal**
In the interest minimizing consumer confusion, we believe it would be appropriate to list out all the active ingredients of the medicines contained in the composite pack. A 6 point Arial font size is proposed for the active ingredient name when the salts/hydrates and quantity of the active ingredients will need to be excluded.

A Main label for a composite pack has been mocked up to show what our proposal would look like (refer to Attachment 10).

There is also currently a lack of information as to how the Medicine Information panel should be set out on the label of the composite pack.

**Proposal**
Rather than having two separate Medicine Information panels for the different medicines within the composite pack, it is proposed that all the information relating to the different formulations are included in the same Medicine Information panel. Where there is specific information relating to the individual medicines eg formulation and
warning statements, this should be called out in the Medicine Information panel.

A Medicine Information panel for a composite pack has been mocked up to show what our proposal would look like (refer to Attachment 11).

<table>
<thead>
<tr>
<th>1108</th>
<th><strong>(20) Registered medicines that require a Medicine Information panel</strong></th>
</tr>
</thead>
</table>
|      | It is noted that the TGA has adopted the US FDA requirements for the ‘Drug Facts’ panel in developing the Medicine Information panel. A study was conducted to compare 8 ‘older’ and 8 ‘newer’ Drug Facts labels (the ‘newer’ Drug Facts labels are those currently used in the US) on OTC non-prescription drugs. The study evaluated participant’s response time and accuracy to answer a series of questions of information based on the different drug labels. Results indicated that participant’s response times were significantly faster with the newer labels compared to the older ones. However this was not true of all OTC product samples (refer to Attachment 12).

Additionally, the TGA has stated in their RIS “A study in 2007 evaluated the effectiveness of the 1999 FDA-mandated standardised format called ‘Drug Facts’ for the labelling of over-the-counter-medicines and compared three labelling formats, the old, new and simulated. They found that consumers preferred the label format with a larger font size over those currently available. In addition, it was noted that the new OTC drug labels may not be easy for some consumers to use and understand, although they are an improvement over old unstandardised labels”.

In principle, we have no objections to the concept of having a standardised Medicine Information panel. However, we question if the US-FDA format is the optimal format, given that there are publications available that demonstrate that consumer comprehension is still an issue.

Consideration should also be given to non-prescription medicine labels that have been developed as a result of consumer testing and have
evidence to show that the labels perform well from a consumer usability perspective. This labelling has been approved by the TGA and is currently on pack for some marketed products.

A side by side comparison of a performance based label and the proposed Medicine Information panel is provided (refer to Attachment 13).

As seen in the example, the use of colours, icons and layout of text on the label which has utilized performance based labelling. JJP believe that the consumer is more easily able to navigate the current label and find the information they are looking for. In comparison with the proposed Medicine Information format, JJP believes that the consumer is more likely to read the current label in the existing format as opposed to in the proposed Medicine Information panel.

JJP does not believe that the draft TGO 79 should attempt to restrict all sponsors/manufacturers to a basic set of requirements for the duration of the Order, as this would limit the sponsors/manufacturers ability to invest in continuing development and enhancement of labelling approaches and designs which would be in the best interests for consumers.

**PROPOSAL**

It is proposed that sponsors/manufacturers who wish to develop and use performance based labelling or other approaches should be provided the opportunity to have these alternate labelling formats and designs considered by the TGA and allowed to be used on their labelling. Rather than making the Medicine Information panel a requirement for all medicines, it is suggested that the Medicine Information panel can be an option which is adopted by sponsors/manufacturers who do not wish to invest in or allocate resources to the development of performance based labelling.

(a) The requirements in this subsection do not apply to: As the current draft TGO 79 does not distinguish between registered
(i) medicines containing substances included in Schedule 4 or Schedule 8 of the Poisons Standard;
(ii) human blood products included in Appendix A of the Poisons Standard;
(iii) medicines for injection;
(iv) the container label for a medicine where subsection 10(14) or 10(15) of this Order applies in relation to the medicine.

PROPOSAL
It is proposed that lines 1110-1111 be changed to:

(a) The requirements in this subsection do not apply to:
   (i) medicines containing substances included in classified as Schedule 4 or Schedule 8 of the Poisons Standard;
   (ii) human blood products included in Appendix A of the Poisons Standard;
   (iii) medicines for injection;
   (iv) the container label for a medicine where subsection 10(14) or 10(15) of this Order applies in relation to the medicine;
   (v) Sunscreens

(b) In addition to the requirements of section 9, the label on the container and label on the primary pack (if any) of a medicine to which this subsection applies must contain an information panel as shown in Schedule 2 of this Order that:
   (i) contains the information required by paragraphs 8(1)(b), (c), (j), (l), and (n); and
   (ii) contains the information required by paragraph 8(1)(k), unless there is a contrary requirement as to the location of a specific sunscreens and other registered medicines, a registered sunscreen would require a Medicine Information panel and the larger active ingredient font sizes. As sunscreens are designated medicines and are often sold in ranges, it is not appropriate that a Medicine Information panel be required and therefore registered sunscreens should be exempted from the label requirements of other registrable products and comply with the same label requirements as for listable sunscreens.

There are substances such as Paracetamol and Ibuprofen that are included in Schedule 4 but also, in some instances to be exempt from scheduling, included in Schedule 2 or Schedule 3 of the Poisons Standard.

PROPOSAL
It is noted that the draft Guideline for TGO 79 states that the Medicine Information panel is only required for the primary label. Clarification should be provided as to whether the TGA intended the Medicine Information panel to apply to the container label and the primary pack (if any) or only on the primary pack.

If the TGA decides to adopt the format of the Drug Facts panel used in the US, the TGA should also align to the US requirements such that a
| warning statement; and (iii) may contain additional information under the heading ‘Other information’. |
| Medicine Information panel would NOT be required on the immediate container when it is enclosed in a primary pack. |
| The current requirements of draft TGO 79 do not require the container label of ‘small’ and ‘very small containers’ to have a Medicine Information Panel. Any container with a volume of 25 mL or higher would therefore require a Medicine Information panel. |
| Labels have been mocked up for different types of medicines which would be required to meet the requirements of subsection 10(20). |
| Refer to: **Attachment 14** for a mock up label of an 80mL medicine  
**Attachment 15** for a mock up label of a 100mL medicine  
**Attachment 16** for a mock up label of a 30g medicine  
**Attachment 17** and **Attachment 18** for mock up labels of medicines that contain a small carton |
| As seen in the examples provided, it would be difficult to fit a Medicine Information panel onto container labels for medicines that contain up to 100mL in volume. |
| The current definition of small and very small containers only considers liquid preparations and fails to consider that if the container is small, any primary packaging is consequently also small in size (e.g. bottle in a carton). Therefore, consideration needs to be given for different labelling types such as (but not limited to) small cartons with limited space on each panel, where it will be difficult to include all the requirements of the draft TGO 79. |
| Although attachments **Attachment 17** and **Attachment 18** show that the small carton label could fit all the requirements of the Medicine Information panel, multiple panels on the carton needs to be used and not all requirements of the TGO 79 can be met. |
To meet the requirements of subsection 10(20), packaging dimensions will need to be increased for smaller container types. This option would however have a significant impact to sponsors and manufacturers as there will be an increase in both manufacturing costs and complexity. Additionally, with the increase in packaging size, pharmacies and grocery channels may not accept the product due to limitations in shelf space. This could potentially result to the product being delisted in stores.

It is also suggested that the Medicine Information panel should be allowed to be truncated or amended, if the space on the medicine packaging does not allow the Medicine Information panel to fit. 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.

**PROPOSAL**

It is proposed that:

- A Medicine Information panel is **NOT** required to be on the immediate container when it is enclosed in a primary pack
- The definition of a small container should be defined as a container which contains less than or equal to 100 millilitres of medicine
- The definition of a small container should be expanded to ensure other small container types such as cartons are captured.
- The Medicine Information panel should be allowed to be truncated or amended, if the space on the medicine packaging does not allow the Medicine Information panel to fit.

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| 1130-1132 | Subject to paragraph (f), the information required by this subsection to be included in the Medicine Information panel is to be presented in black text with white background. |

It should be noted that the use of different coloured background can increase the readability of the text.

**PROPOSAL**

Different contrasting text and background colours should be allowed, as
Refer to Attachment 19 for examples of US artwork which shows different colours being used for the Drug Facts panel.

1133-1139

(e) The information, when required, is to be presented in the following order in the Medicine Information panel under the headings: Ingredients, Uses OR What this medicine is used for, Warnings, Directions for use, Other information.

(f) The headings Ingredients, Uses OR What this medicine is used for, Warnings, Directions for use and Other information in the Medicine Information panel are to be highlighted by the use of bold fonts, shading, box-borders, colour or by other suitable means.

The current wording could be interpreted such that ‘Uses OR What this medicine is used for’ is one heading.

It is noted that the wording in the draft Guidance Document states ‘Uses’ or ‘What this medicine is used for’ which is easier to understand that there are two different headings which can be used.

**PROPOSAL**

To ensure the requirement is not misinterpreted, it is proposed to change lines 1133-1139 to:

(e) The information, when required, is to be presented in the following order in the Medicine Information panel under the headings: ‘Ingredients’, ‘Uses’, OR ‘What this medicine is used for’, ‘Warnings’, ‘Directions for use’, ‘Other information’.

(f) The headings ‘Ingredients’, ‘Uses’ OR ‘What this medicine is used for’, ‘Warnings’, ‘Directions for use’ and ‘Other information’ in the Medicine Information panel are to be highlighted by the use of bold fonts, shading, box-borders, colour or by other suitable means.

1152-1153

(k) The Medicine Information panel must not be broken up by non-mandatory information, logos or graphics.

The use of graphics within the Medicine Information Panel should be allowed as long as the Medicine Information panel is not broken up.

Graphics relating to usage and opening instructions may also provide a clearer form of communication as opposed to having text.

Dangerous Goods symbols should also need to be considered to ensure the requirements of the Australian Dangerous Goods Code can be met. These symbols have prescribed sizes and may potentially break up the
Consideration also needs to be given to barcodes and allocated coding areas (for batch and expiry information). The position or dimensions of these elements are often fixed and cannot be altered.

The Medicine Information panel may be broken up by the barcode especially on small cartons and primary labels on bottles, where the barcode can only fit in the panel which contains the Medicine Information Panel. Barcodes also need to be a certain size to meet GS1 requirements otherwise the product will have the risk of not being ranged in retailers.

A mocked up label of a Medicine Information panel has been provided to show how a barcode will break up a Medicine Information Panel (refer to Attachment 20).

Labels may also have allocated embossing/debossing areas (based on the printing capabilities) for batch and expiry information which could potentially break up the Medicine Information Panel. In the case where the batch and expiry information breaks up the Medicine Information panel, there should be an allowance for this to ensure that tooling and printing machinery are not required to change.

<table>
<thead>
<tr>
<th>1163-1177</th>
<th>11 How information is to be expressed (1) Use of appropriate metric units</th>
</tr>
</thead>
<tbody>
<tr>
<td>1163-1177</td>
<td><strong>(a)</strong> For active ingredient(s), where a particular is a statement of mass for which there is a metric unit of measurement, the metric units must be expressed as follows:</td>
</tr>
<tr>
<td></td>
<td>(i) a statement of quantity for 1 microgram up to 999 micrograms inclusive must be expressed in terms of micrograms;</td>
</tr>
<tr>
<td></td>
<td>(ii) a statement of quantity for 1000 micrograms may be expressed as either 1000 micrograms or 1 milligram;</td>
</tr>
<tr>
<td></td>
<td>It is noted that in the TGO 79 guidance document, the TGA allows microgram to be abbreviated to ‘mcg’. Based on the National Measurement Regulations 1999 ‘mcg’ is not a legal Australian unit of measure. Additionally, there is a potential risk that a consumer would interpret the abbreviation to be milligram.</td>
</tr>
<tr>
<td></td>
<td><strong>PROPOSAL</strong></td>
</tr>
<tr>
<td></td>
<td>In the interest of minimizing consumer confusion, it is proposed that for quantities that are less than 1000 microgram, there should be the option to express the quantity statement as milligrams or micrograms eg 500microgram or 0.5milligram.</td>
</tr>
<tr>
<td>(iii)</td>
<td>a statement of quantity for more than 1 milligram up to 999 milligrams inclusive must be expressed in terms of milligrams;</td>
</tr>
<tr>
<td>(iv)</td>
<td>a statement of quantity for 1000 milligrams may be expressed as either 1000 milligrams or 1 gram; and</td>
</tr>
<tr>
<td>(v)</td>
<td>a statement of quantity for more than 1 gram up to 999 grams inclusive must be expressed as grams.</td>
</tr>
</tbody>
</table>

This statement could be interpreted such that the quantity statement must be consistent with the unit of measurement used in any warning statement required for an ingredient.

**PROPOSAL**

To ensure that the quantity statement on the medicine will comply with the requirements of the National Measurement Institute, it is proposed that lines 1192-1194 be changed so that the unit of measurement used in the warning statement reflects that unit of measurement used in the quantity statement.

| (d) | Where the information is a statement of mass or volume, the unit of measurement must be consistent with the unit of measurement used in any warning statement required for that ingredient. |

Consideration needs to be given to medicines which have the same active ingredient in different strengths and the dosage volume is not consistent between the two strengths.

**Example:** Where the dose volume is 5 mL, and there are strengths of 1 mg/mL and 5 mg/mL, these must be labelled as 5 mg in 5 mL and 25 mg in 5 mL, respectively.

| (ii) | in the case where the liquid for ingestion is one of a series of strengths containing the same active ingredient – as the quantity of the active ingredient contained in the stated volume of a suitable dose of the liquid with the quantity or proportion of active ingredient expressed consistently across the series in terms of the same stated dose volume. |

Example: Where the dose volume is 5 mL, and there are strengths of 1 mg/mL and 5 mg/mL, these must be labelled as 5 mg in 5 mL and 25 mg in 5 mL, respectively.

| 1208-1215 | Consideration needs to be given to medicines which have the same active ingredient in different strengths and the dosage volume is not consistent between the two strengths. |

Eg

**medicine 1:** Pholcodine 1mg/mL, 15mL dosage

**medicine 2:** Pholcodine 4mg/mL, 3.75mL dosage

In order to meet the requirements of subsection 11(2)(c)(ii), using 5mL as the same stated dose volume, the quantity of the active ingredient in medicine 1 would be stated as ‘Each 5mL contains Pholcodine 5mg’ and medicine 2 would be stated as ‘Each 5mL contains Pholcodine 20mg’.

By expressing the active ingredient ‘consistently in terms of the same stated volume dose’, there is the risk that a consumer would look at the active ingredient quantity statement for medicine 2 and interpret ‘Each
5mL’ to be the dosage instruction. *This could potentially lead to an overdose of the active ingredient as the consumer would have taken an extra 5mg of Pholcodine per dosage compared to the intended 15mg of Pholcodine from a 3.75mL dose.*

**PROPOSAL**
To ensure the information is not interpreted incorrectly by the consumer, it is proposed that the stated volume for a liquid for ingestion be changed to mg in 1mL. By standardising the expression of the active ingredient to ‘mg/1mL’ this will also prevent any variations of how the active ingredient is expressed between different sponsors.

Additionally, it should be noted that the dosage of the medicine can vary depending on the target population (e.g., children’s dosage vs adult dosage) and it would be unclear as to what dosage should be used in expressing the active ingredient.

**PROPOSAL**
To provide further clarification, the definition of a ‘suitable dosage’ should be defined in the TGO.

1235-1237 *(e)* for a transdermal patch, intrauterine drug delivery system or implant - as the total quantity of the active ingredient in each patch, drug delivery system or implant and the quantity of the active ingredient released in a stated time;

JJP believes the TGA’s intentions were to have the information in subsection 11(2)(e) in 6 point Arial, however in the case that this information is provided on the main label, it can be interpreted that the ‘quantity of the active ingredient released in a stated time’ is required to be in the same point size as the active ingredient quantity (15 point Arial - subsection 9(7)) when the information is expressed on the main label.

**PROPOSAL**
A statement should be provided in the TGO 79 or in the ‘Guideline for the labelling of Medicines’ document to ensure that a text size equivalent to 6 point Arial is allowed when the ‘quantity of the active ingredient release in a stated time’ is included on the main label.
Overview
As there have been many comments and proposals made in relation to the draft TGO 79, it is anticipated that changes in the TGO 79 will be made. Subsequently, the Guideline will need to be updated to reflect the changes made to the TGO 79.

However at this point in time, this document includes Johnson & Johnson Pacific’s comments and proposals in response to the draft Guideline for the labelling of medicines – Version 1.0, August 2014.
Introduction

Comments:
The draft TGO 79 does not include the definition of words that are already defined in the Therapeutic Goods Act 1989, it is suggested that all the words and their full definition from ‘Section 6 Interpretation’ of TGO 79 be included into the Guidance document. This will help sponsors and manufacturers to have quick access to the interpretation of words without the need to refer to the Therapeutic Goods Act.

2.1 General requirements

The TGA will judge the acceptability of fonts by superimposing the labelling text in the font chosen by the sponsor onto the text in Arial.

Comments:
It is unclear how the TGA will judge the acceptability of fonts. In the case that the TGA will be using a tool or a program to review the fonts, the same tool or program should be made available to the sponsors and manufacturers of medicines. Additionally, as different fonts are identified as being acceptable, a commitment from the TGA should be provided such that a list of fonts that have been deemed acceptable will be included in the guidance document.

2.2.3 Information on a label

All of the above need to be legible for the shelf-life of the product [section 7(2)(c)]; to achieve this, it is recommended that you use ink instead of embossing.

Comments:
To ensure that manufacturers will not require capital investment to set up new equipment that will print information such as batch and expiry onto the labels, the use of embossing, debossing and crimping should remain acceptable as long as the text is information is legible and remains clearly visible for the shelf life of the product.

3.1 How the name is displayed

When a registered medicine contains two or three active ingredients and it is impractical to fit the names and quantities of all the active ingredients on a single line on the main label, display the names and quantities of the active ingredients on more than one line.

- Place the names of the active ingredients immediately below the name of the medicine [section 9(3)(a)].
- Make the names appear as a cohesive unit [section 9(2)].
- Do not interrupt the names with other information or graphics [section 9(2)].

Comments:
The information above refers to the active ingredient rather than the medicine name. This information should be moved into section ‘3.2 Names of active ingredients’.
3.4.1 Names for registered medicines

For registered medicines with less than four active ingredients, the names and quantities of the active ingredients must be in a sans serif font at least the equivalent of 15 point Arial on the main label [subsection 9(7)a].

If a registered medicine has at least four active ingredients, the font size of the names and quantities of active ingredients depends on whether there is a Medicine Information panel:

- no Medicine Information panel (prescription medicines): in a sans serif font the equivalent of at least 12 point Arial on the main, side or rear label [subsection 9(8)a]
- with Medicine Information panel (most registered non-prescription medicines): in a sans serif font the equivalent of at least 6 point Arial within the medicine information panel.

Comments: As discussed in our response to the TGO 79 draft, a font size of 10 point Arial has been proposed for the active ingredient name when placed on the main label. This proposal is based on the assumption that the salt/hydrate component of the active ingredient and quantity statement of the active ingredient are not required to be included on the main label. In the case that the salt and quantity statement of the active ingredient will be required to be included on the main label, a font size of 8 point Arial has been proposed.

Guidance on how the names of active ingredients in Composite Packs are to be included on the main label should also be included. Using an example of a Composite pack which contains medicine 1 (4 active ingredients) and medicine 2 (3 active ingredients), it is unclear whether this Composite pack is considered to have 7 active ingredients in total and therefore all the active ingredient can be place in the medicine information panel or whether the only active ingredients to be included on the main label are the active ingredients from medicine 1, since it only contains 3 active ingredients.

Additionally, it is not clear whether ‘Registered complementary medicines’ would be required to meet subsection 9(7). A statement of clarification should be included in this section.

3.4.2 Names on small and very small containers

On small containers (2.5 – 25 mL capacity), the font size of the name of the medicine and the names of the active ingredients is to be at least the equivalent of 8 point Arial and the quantity of active ingredients is to be at least the equivalent of 6 point Arial, provided that the container is in a primary pack with font size that complies with TGO 79 [subsections 10(4 and 14)].

Comments: The current requirements of TGO 79 would require primary packs of ‘small containers’ to include the active ingredient name on the main panel in a font size of 15 point Arial, however the corresponding primary packs will in most cases match the size of the immediate container and it would be difficult to meet this requirement. As discussed in our response to TGO 79 document, a font size of 8 point Arial has been proposed for the active ingredient name when included on the primary pack of a ‘small container’.
4.1 Salts, hydrates and solvates

Comments:
It is evident that the TGA’s objective with proposing the requirements in the draft TGO79 is to reduce consumer confusion. In the interest of trying to meet this objective, JJP is proposing that the salt and hydrate component is excluded from the active ingredient name on the main label. In the case that the active ingredient is the salt (e.g. calcium carbonate in antacids), it would be appropriate for the full active ingredient to be used when included on the labels.

In the first two bullet points, it is unclear why the statement ‘on all panels of the primary pack label’ has been included as this is not a requirement in the TGO 79. Additionally, it would not be practical to include the name of the active ingredient on every panel of the primary pack.

4.3 Metric Units

Express quantities using appropriate metric units [section 11(1)].

If possible, write the units in full. If you use an abbreviation, this is expected to be in standard SI abbreviations and symbols.

We recommend that for the word ‘microgram’, if there is insufficient space for the full word, use the abbreviation ‘μg’. You may also use ‘mcg’ for medicines that are not prescription medicines. If there is sufficient space on the primary pack for the full word, but not on the container, then we recommend that you use the abbreviation on the container and ‘microgram (μg)’ or ‘microgram (mcg)’ on the primary pack.

Comments:
As discussed in our response to the TGO 79 draft, the inclusion of a non-metric measure should be allowable, as long as there is the mandatory metric measurement eg 300mL (33 Fl. oz).

Although the guidance document allows microgram to be abbreviated to ‘mcg’, it should be noted that based on the National Measurement Regulations 1999, ‘mcg’ it not a legal Australian unit of measure. There is also a potential risk that a consumer would interpret the abbreviation to be milligram.

4.6 Ethanol

If ethanol is present at 3% v/v or more, then the quantity of ethanol must be declared on the label as % v/v [Schedule 1 of TGO 79].

Comments:
It is noted that in TGO 69, when the ethanol content was higher than 3%, there was only the requirement to include the statement “contains ethanol”. In the draft of TGO 79, it is unclear why the quantity of ethanol would now be required to be declared on the label and what added benefit this would have for a consumer.

Consideration needs to be given to products such as tinctures, where the ethanol quantity included in the formulation as a ‘qs’ amount. As the ethanol quantity may vary from each batch, it would be difficult to include an accurate %v/v on the label.
It is proposed that the declaration of %v/v of ethanol on the label to be excluded when the quantity of ethanol added into the formula as ‘qs’ in preference for a statement of “contains ethanol”.

4.8 Sodium and potassium in oral medicines

For sodium and potassium in oral medicines, there is a requirement for quantification in milligrams of elemental sodium or potassium. This requirement applies when the daily dose contains more than 39 mg (1 mmol) potassium or more than 120 mg sodium [Schedule 1 of TGO 79].

Comments:
It is unclear why the quantity of sodium or potassium would now be required to be declared on the label and what added benefit this would have for a consumer.

As there are medicines which include an overage for potassium and sodium, it would be difficult to include the information on the label, as the amount of potassium and sodium used would vary from each batch.

It is suggested that the guidance document ensures that calculation of potassium or sodium is to be based on the label claim or if there are clinical implications in only declaring the “label claim, a range might need to be considered as being appropriate.

5. Use of colour

Our recommendations with respect to colour are similar to those of the FDA <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm349009.pdf>.

Comments:
It is noted that the FDA document is a draft version. Further, reliance on a guidance document from a regulator located overseas will require consultation prior to adopting these guidelines, similar to the current practice for adopting European guidelines.

6.1.1 Font size of names

For registered medicines with less than four active ingredients, the name and quantity of the active ingredients is to be in a sans serif font at least the equivalent of 15 point Arial on the main label [subsection 9(7)(a)].

Comments:
As discussed above, a font size of 10 point Arial has been proposed for the active ingredient name on the main label. This proposal is based on the assumption that the salt/hydrate component of the active ingredient and quantity statement of the active ingredient will not be required to be included on the main label. In the case that the salt and quantity statement of the active ingredient will be required to be included on the main label, a font size of 8 point Arial has been proposed.

For a small container that contains primary packaging, the primary packs will in most cases match the size of the immediate container. It would therefore not be feasible to use a font size of 15 point Arial.
A font size of 8 point Arial is proposed for the active ingredient when it is listed on the corresponding main label of the primary pack for small containers.

**6.2 Registered non-prescription medicines – Medicine Information Panel**

Comments:
As discussed in our response to the TGO 79 draft, a Medicine Information panel should **NOT** be required on the immediate container when it is enclosed in a primary pack. Additionally, consideration needs to be given for different labelling types such as (but not limited to) small cartons with limited space on each panel, where it will be difficult to include all the requirements of the draft TGO 79. If the space on the medicine packaging does not allow the Medicine Information panel to fit, the Medicine Information panel should be allowed to be truncated or amended. Flexibility to the use of colours and the appearance of the Medicine Information panel also needs to be considered.

**6.2.3 Only include required information**

*The medicine information panel must not be broken up or interfered with by logos or graphics. It may contain information that is not required by TGO 79, but the optional heading ‘Other information’ must be used [section 10(2)(b)(iii)].*

Comments:
The use of graphics within the Medicine Information Panel should be allowed as long as the Medicine Information Panel is not broken up. Consideration also needs to be given for Dangerous Goods symbols, barcodes and allocated coding areas for batch and expiry information which may potentially break up the Medicine Information Panel. The position or dimensions of these elements are often fixed and cannot be altered.

**6.2.5 Use of coloured or bold text**

*With the exception of headings, all information in the Medicine Information panel must be black text against a white background [section 10(20)(d)].*

Comments:
Different contrasting text and background colours should be allowed, as long as the text is clearly visible and legible.

**6.2.10.5 Dosing for liquid, solid or semi-solid products**

*Do not state the dosage in terms of culinary ‘spoonfuls’ (e.g. teaspoon, dessertspoon, tablespoon etc.); these spoons are not standardised or calibrated.*

Comments:
In the scenario that a calibrated measuring spoon is provided with the medicine, guidance should be given as to how the dosage term should be stated.
6.2.12 Continuation of the medicine information panel

For situations when more than one additional panel is used, we recommend that you mark the direction of the continuation with arrow heads (▷ or ◄) at the end of ‘continued...’.

Comments:
The typographical error ‘wer ecommended’ should be corrected.

6.2.13 Examples of Medicine Information panels

Comments:
The examples of the Medicine Information panels provided do not meet the requirements subsection11(10)(g) of the TGO 79 i.e the text size used for the subheadings under the warnings heading is not smaller than the text size used for the headings. The examples should be updated to reflect the requirements of the TGO 79.

Additionally, a Medicine Information panel that has been separated into two columns on the same panel (as shown below) and a Medicine Information for a composite pack should be provided as examples.

![Example Medicine Information Panels]
6.2.13.4 Examples of clear directions for use

**Medicine Information**

**Ingredient(s)**
- Each mL contains 0.5mg oxymetaxoline hydrochloride
- Also contains benzalkonium chloride as a preservative.

**Uses**
- For symptomatic relief of nasal and nasopharyngeal congestion associated with the common cold, hayfever and sinusitis.

**Warnings**
- Do not use
  - in children under 6 years of age
  - for more than 3 days
- Ask your doctor or pharmacist before use if using for children between 6-12 years of age
- Consult a doctor if congestion persists

**Directions for use**
- Adults and children over 6 years of age: 2-3 sprays in each nostril every 10-12 hours as necessary. Maximum 2 doses in 24 hours.

Comments:
The use of ‘0.5mg’ is not consistent with the requirements of TGO 79. The 0.5mg in the example should be changed to 500 microgram.

6.5 Medicine kits and starter packs

Comments:
As medicine kits are classified as Listed Goods, information should be included in this section to ensure that the label on the package that, together with medicines, constitutes a medicine kit would not require:
- The name and quantity or proportion of all active ingredients in each of the medicines within the kit to be included on the main panel of the primary pack (assuming the Medicine Kit was packaged in a primary pack).
- The name and quantity or proportion of all active ingredients in each of the medicines within the kit to be included in 15 point Arial.
- A Medicine Information Panel.

9.8 Individually wrapped medicines

*a transdermal patch, after application to the patient, must be identifiable by a code, name of medicine, or name of active ingredient [section 10(16)(c)].*

Comments:
The reference to section 10(16)(c) of TGO 79 should be changed to 10(16)(d). The statement above should also be moved into section ‘9.9 Transdermal patches, intrauterine or implanted drug delivery systems’.
As discussed in our response to the TGO 79 draft, it is proposed that transdermal Nicotine Replacement Therapy products be exempt from the requirements of subsection 10(16)(d) since the products can already be identified by the brand name and the inclusion of the strength of the active ingredient will have no added benefit to the consumer or health care professional.

9.10.1 Requirements for blister, strip and dial packs

Where it is not possible to apply all the information over each blister pocket, a random display of the information should appear frequently across the blister pack.

Comments:
To ensure that scatter printing can still be used for blisters, it is proposed that the sentence above is changed to:

‘Where it is not possible to apply all the information over each blister pocket, a random display of the information should appear frequently across the blister pack. This can be achieved by the use of scatter printing.’

9.11 Small and very small containers

Less content is required on the labels of small (2.5 – 25 mL capacity) and very small containers (no bigger than 2.5 mL capacity), and the required font sizes are smaller than for larger containers, provided that the containers are in a primary pack that complies with TGO 79.

Comments:
As discussed in our response to the TGO 79 draft, the current requirements of draft TGO 79 requires containers with a volume of 25 mL or higher to contain a Medicine Information panel. However, as seen in the examples provided in our response to the TGO 79 draft, it would be difficult to fit a Medicine Information panel onto container labels for medicines that contain up to 100 mL in volume. It is therefore proposed that the definition of a small container should be defined as a container which contains less than or equal to 100 mL of medicine.

Additionally, the current definition of small and very small containers only considers liquid preparations and fails to consider that if the container is small, any primary packaging is consequently also small in size (e.g., bottle in a carton). Consideration needs to be given for different labelling types such as (but not limited to) small cartons with limited space on each panel, where it will be difficult to include all the requirements of the draft TGO 79.

Section 9.11 of the guideline will need to be updated to reflect the changes made to the TGO 79.

11.1 Changing sponsor

If the receiving sponsor chooses to supply medicine bearing the relinquishing sponsor’s name and contact details on the label, this is acceptable for a period of up to 12 months [section 8(ii) of TGO 79].
Comments:
As discussed in our response to the TGO 79 draft, the timeframe for changing sponsor details should not be defined, on the provision that the ‘receiving sponsor’ has mechanisms in place, such that they can be contacted by consumers, regulators and health care professionals.

Additionally, [section 8(i) of TGO 79] should be corrected to [section 8(1)(i) of the TGO 79].

11.2 Changes in formulation or appearance

*If a medicine has been marketed in Australia and you change the appearance of the medicine, we recommend including the statement ‘New Appearance’ on the label to alter consumers*

*If the formulation is changed and the appearance has not changed, we recommend including the statement ‘New Formulation’ on the label.*

Comments:
While we agree with the recommendation to include ‘New Appearance’ or ‘New Formulation’ on the label where relevant, this recommendation cannot become a requirement for the approval.

*For registered medicines, we expect your application to include a justification of the time period that the statement ‘New Appearance’ or ‘New Formulation’ will remain on the label. Usually, this time period would correspond to one shelf-life cycle.*

Comments:
A definition for ‘shelf-life cycle’ should be provided in the guidance document. Our interpretation of a ‘shelf life cycle’ is the shelf life of the product and not the shelf life of the first batch produced which contains a statement of ‘New Appearance’ or ‘New Formulation’ on the label.

Consideration for slow moving, seasonal medicines and medicines that are only manufactured once a year needs to be given.

Additionally, clarification should be provided as to whether the shelf-life cycle should apply from the date that the stock is released by the manufacturer or stock released by the companies controlled warehouse.