

Document(s): *Therapeutic Goods Order No.91- Standard for labels of prescription and related medicines (TGO 91)*

I consider the proposed TGO 91 acceptable in its present form

I consider the proposed TGO 91 acceptable “as is” but I have proposed minor suggestions for improvement*

**Please refer to my response below*

I do NOT consider the proposed TGO 91 acceptable in its present form, and I have proposed various responses for consideration*

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Page no.	Section	Issue/Item	Suggestion/Response:
13	8(1)(j) – information to be included on the label	<p>Bayer notes that subsection 8(1)(j) of TGO 91 does not provide Sponsors the option to meet the specified labelling obligations where the container is included in a primary pack.</p> <p>Also, the number of declarable ingredients and residual substances listed in Schedule 1 of the labelling order has increased. For products that come in small packs without a leaflet, declaring “TGO 91-Schedule 1” substances on the main label could present space constraints, especially if they contain multiple active ingredients or proprietary ingredients. This may therefore, necessitate the inclusion of a leaflet in the pack, which will add to the production costs of some medicines.</p>	<p>Bayer proposes extending this labelling obligation so as to apply to the primary pack label instead of the container label when the medicine container is packaged in a primary pack. This will ensure pharmacists can readily and easily identify excipients which may need to be avoided in certain patients.</p> <p>In addition, Bayer would appreciate TGA’s flexibility for size of text and layout, which needs to be considered when the pack size is quite small or when multiple excipients are required to be listed and the space on the label is limited.</p>
15	9(5) – information to be	In section 9(5) of TGO 91 it is stated that “the name of the active ingredient(s) and the quantity or proportion of active ingredient(s) must be	Bayer would like more clarification on why this change is being proposed. What is the added benefit to consumers? Bayer’s concern is that consumers might be confused with

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	included on the main label	displayed in a text size of not less than 3.0 millimetres”.	<p>higher prominence of complicated active ingredient names, especially when there are multiple brands or generics of the same active ingredient. Given this labelling order focuses on prescription products, the prescribing decision has already been made for the patient prior to the patient accessing the information on the product label. In addition, for a product with multiple active ingredients and very long active ingredient names (for example Yaz Plus - mock up artwork as Attachment 1 below) this occupies a very large portion of space on the label and takes emphasis away from more patient critical information e.g. storage conditions, directions for use or dosage form.</p> <p>Bayer would also like to emphasise that pharmacists stock products in the pharmacy by trade name and hence prominence of the active ingredient is at no added benefit in a pharmacy setting either.</p> <p>Recommendation: Revert to the text size of the active ingredients to 1.5 mm on the main label.</p>
19	10 – small containers (not including injections)	Requirement to display name of medicine and the name(s) of all active ingredients in a text size of not less than 2.0 millimetres.	<p>It will be difficult to achieve an increase in font size from 1.5 mm to 2.0 mm on small containers. As a result there may be low compliance with this requirement leading to an increased need for labelling exemptions and inconsistent practices, not to mention an unintended consequence of increased regulatory burden.</p> <p>Recommendation: Revert to the text size of the active ingredients to 1.5 mm on the main label.</p>

Document(s): *Therapeutic Goods Order No.92- Standard for labels of prescription and related medicines (TGO 92)*

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I consider the proposed TGO 92 acceptable “as is” but I have proposed minor suggestions for improvement*

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12	7 (3) General Requirements including label presentation	Relating to compliance with advertising requirements, in particular Part 5.1 of the Act/Regs and the applicable provisions of the Therapeutic Goods Advertising Code	It is unclear what this section means. Bayer suggests rewording.
14	Section 8(1)(m) – If the medicine requires some preparation, such as dissolving, suspending, reconstituting etc. – instructions for its preparation and where relevant a statement of conditions of storage and the maximum period of storage between preparation and use.	Bayer is concerned that as written, the requirement to include additional information such as conditions of storage and maximum period of storage between preparation and use could be applied to soluble vitamins for immediate use.	The words “where relevant” in 8(1)(m) qualify the requirement somewhat but Bayer believes that additional qualifications may be useful, such as “except where the product is intended for immediate use” or similar.

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15	Section 8(2)(a) & (b)	<p>The requirement for the MIP applies to registered complementary medicines. In Bayer's case we have a registered complementary medicine with 19 active ingredients. Fitting in all these ingredients and other required information into a MIP will be an issue for a starter pack, despite not meeting definition of small label</p>	<p>See Attachment 2 for mock ups and there is no issue space wise accommodating a MIP for 30 tablet pack size for Elevit despite containing 19 active ingredients. However for a very small starter pack of 5 tablets, despite the carton not meeting the definition of a small container, it will be hard to fit in a MIP due to the large number of actives. Available space for a MIP is on the back of the carton only as side panels are very narrow and not suitable for a table (see Attachment 2). The back carton panel is only 36cm² and trying to accommodate 19 active ingredients including long salt names plus other information required in a MIP panel into this confined space is highly unlikely to be achievable. Having to apply for a section 14 for this Starter pack size is not desirable. This issue is likely to recur with other registered complementary multivitamin products which by nature include many ingredients, particularly for smaller pack sizes such as starter packs.</p>
15	Section 8(2)(f) – “Other information” allows only storage conditions, packaging features, names of excipients and sponsor details (shown as A, B, C, D) in MIP	<p>Bayer has concerns that the MIP sub-heading of “Other information” may not allow information such as “sugar free” “gluten free”, cultural/religious (e.g. halal,) etc.</p> <p>It should be noted that queries such as “Does this product contain....” Are the most frequent consumer questions to call centres and consumers actively look for it on packs to assist with their purchasing decisions.</p>	<p>The TGA should allow additional information that is important to consumers to appear in this section, such as absence of certain excipients.</p>

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		<p>With the increased pressure for space on the label, the sub heading “Other information” is a logical place to include this information, given that the available front of pack space will be diminished given the increased prominence of the active ingredients and other limitations on design.</p>	
15	<p>Section 8(3) – If the registered medicine is (i) a medicated throat lozenge, or an inorganic salt-based antacid that is in a solid dosage; and (ii) space available for a label on the primary pack is less than 70 cm², or (b) it is intended for use as a skin antiseptic by a HCP as either a hand hygiene or patient pre-op prep, then subsection (2) (MIP) does not apply</p>	<p>Section 8(3)(a) & (b) does not consider that many products other than medicated throat lozenges and inorganic salt-based antacids will have difficulty including the requirements of section 8(2) (Medicines Information Panel) when the space available for a label on the primary pack is less than 70 cm². Space limitations on labels are not specific to throat lozenges, antacids and hand-hygiene products used by health care professionals.</p> <p>It should be noted, that wording “space available label on the primary pack is less than 70 cm²” is unclear – does this mean a) the actual current label size is less than 70 cm² or b) the surface area of the actual primary pack is less than 70 cm². This would mean that the available label size (if the primary pack is the actual container) is likely to be a lot less and it will be harder to fit in the MIP. There shouldn’t be an expectation that sponsors increase the size</p>	<p>The exemption from the requirements in section 8(2) should be allowed for <u>all</u> non-prescription products with primary pack labels less than 70 cm² and should not be limited to medicated throat lozenges and inorganic salt-based antacids, as other products will have similar difficulties complying. For example starter pack of Elevit as per above.</p>

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		<p>of their label to accommodate the requirements – this is often not technically feasible.</p>	
16	<p>Section 9(3) – The name of the medicine and the name(s) of the active ingredient(s) must on the main label: (b) not be separated by any text or graphics, except where additional information is required by subparagraphs 11(2)(i)(i) or 11(2)(i)(ii) or in relation to medicines contained in a composite pack or a medicine kit.</p>	<p>Is the intent of Section 9(3)(b) to exempt products containing herbal medicines, and composite packs and medicine kits from displaying active ingredients directly underneath the name of the medicine? The wording of this section is not clear if status quo (as per TGO69 requirement) remains for products with these type of ingredients – i.e. can active ingredients in these type of products appear anywhere on the main label and not have to be directly under medicine name? What about a product that contains one herbal ingredient and one vitamin, does only the active ingredient that isn't herbal need to appear directly under the name of the medicine and the herbal ingredient can appear anywhere or can all ingredients be placed together anywhere on the main label? 2nd option makes more sense.</p> <p>Bayer also feels the prescriptive nature of this section will interfere with the display of graphics on the main label which often indicate to the consumer in an easy to understand way what the product is to be used for. The minimisation of graphics makes self-selection of relevant products harder.</p>	<p>Please refer to Attachment 3 for an example of a registered medicine complying with TGO 92 where graphics and therapeutic area indicators have had to be minimised and made much less prominent to accommodate the increased prominence of 3 active ingredients. The focus on this label as per TGO92 now is on harsh sounding chemical names that arguably do not provide much value to consumers. We therefore believe this section on design is better suited to the Guideline rather than the Order.</p>

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17	Section 9(7)(a) – If the medicine is intended to be, or is, registered goods, then (a) where the medicine contains three or fewer active ingredients, the name(s) and quantity or proportion must be displayed on the main label in a text size of not less than 3mm.	<p>Bayer believes that the TGA has not adequately addressed concerns about font / text size that were described in detail in Bayer’s submission on the draft TGO 79 in November 2014.</p> <p>In that submission, Bayer stated that for many products particularly those where the label dimensions are small, a 15 point font size is difficult to meet for all products (15 point font as per TGO79) and hinders consumers self-selection of non-prescription medicines as more valuable information regarding what the medicine is used for has to be reduced in prominence.</p>	<p>Bayer proposes that 2mm is a more suitable font size than 3mm to allow most products with limited label space and up to 3 active ingredients enough space to maintain branding and provide important information to consumers re the condition the product is to be used for.</p> <p>The option of including the name of the active moiety only on the label as described in section 9(7)(d) – as a way of shortening the amount of text and thereby allowing an increase in font size – is not an option that is available to Bayer products that are harmonised with New Zealand as this way of expressing active ingredients is not permitted by Medsafe requirements.</p> <p>The text size requirement of the TGO 92 must therefore be appropriate to allow full names and strengths of active ingredients to be shown, so that we can continue to harmonise and supply products in New Zealand.</p>
17	Section 9(7)(c) – Where the medicine contains four or more active ingredients, and subsection 8(2) (MIP) applies, then compliance with 9(1)(b) and 9(1)(c) is not required	<p>Bayer interprets this section as meaning that where there are four or more active ingredients and these are displayed in the Medicines Information Panel, then the names and quantity or proportion of active ingredients are not required on the main label.</p> <p>Bayer believes this is reasonable. However, it is unclear how this relates to composite packs such as Day and Night cough, cold & flu tablets, where the same</p>	<p>It should be made clear that section 9(7)(c) also applies to composite packs where there are four or more active ingredients even if one or more of the actives are the same in the day and night tablet .</p>

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		active ingredient(s) may be present in both day and night tablets (example – phenylephrine, paracetamol).	
19	Section 10(7) Small containers	<p>While Bayer does not object to the requirements for labelling of small containers, we have concerns that the corresponding primary pack which is also generally small will have difficulty in complying with sections 8 and 9.</p> <p>Bayer also queries the possible impact of section 10(7) (as written) on listed medicines. The text size of active ingredients in listed medicines is allowed to be not less than 1.5 mm; however listed medicines in small containers would require active ingredients to be not less than 2 mm. We suspect this may be a drafting error.</p>	<p>Please refer to Bayer comments relating to text size for section 9(7)(a).</p> <p>Bayer feel that unless the minimum text size required by section 9(7)(a) is reduced, the definition of a “small container” should be amended. Bayer has previously nominated labels of 70 cm² or less as those that will have difficulty complying with a 15 point text size and expect the same to occur with 3mm requirement.</p> <p>Bayer recommends that the TGA re-examine the issue of labels with small dimensions.</p> <p>Bayer recommends that TGA examine the impact on listed medicines and correct any drafting error.</p> <p>Bayer believes that the TGA has not adequately addressed the issue of achievable text size in the draft TGO 92.</p>
24	Section 11(2)(d) – Where a medicine is to be prepared before use and is a liquid for ingestion – (a) label must state the quantity of active ingredient contained	<p>Bayer queries the possible impact of section 11(2)(d) on products such as hot drink sachets, soluble vitamins, soluble aspirin and others.</p> <p>The wording of this section implies that labelling should specify the amount of active ingredient in, for example, a 250mL mug of hot water, a 250 mL glass of water (or</p>	<p>TGA may consider re-drafting to exclude possible impact on these types of products.</p>

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	<p>in the stated volume of a suitable dose of liquid after preparation as per label instructions</p>	<p>similar). These products are generally discrete dosage units however the wording suggests that the labelling should specify the quantity of the active ingredient contained in the stated volume of a suitable dose of the liquid after preparation. This presents a problem for soluble tablets and powders in sachets, where the consumer does not measure out an exact dose of liquid.</p>	
<p>25</p>	<p>Section 11(2) Expression of quantity or proportion of active ingredients 11(2)(i)(i) where the active ingredient is a herbal material, such as a dry, fresh, milled or powdered herb, as the weight of the herbal material: except where standardisation is claimed on the label, then the minimum dry or fresh weight of herbal material and also the quantity of standardized</p>	<p>Inclusion of the input amount of the herbal material is not helpful to the consumer. This will create confusion regarding which aspects of the content to compare, are not reflective of traditional dosage information that relates to the equivalent dry or fresh herbal weight, and does not differentiate between the native herbal extract and the herbal preparation with carriers to ensure stability and content uniformity. The herbal preparation amount is frequently not relevant to the evidence therefore this label information is adding additional complexity to the label for negligible benefit to the average consumer, when this information is readily available on the public ARTG entry for those consumers that are particularly interested and have the knowledge to interpret this information.</p>	<p>The TGA should consider redrafting to exclude “in addition to the requirements of paragraph 11(2)(a)” so that the amount of the active ingredient or herbal preparation is not required to appear on the label.</p>

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	<p>constituent(s) in the herbal material: 11(2)(i)(ii) where the active ingredient is a herbal preparation as the dry or fresh weight of the herbal material from which the preparation was derived except: 11(2)(i)(ii) (a) where standardisation of the herbal preparation is claimed on the label, then, the minimum dry or fresh weight of herbal material from which the preparation is derived and the quantity of standardised constituent(s) in the herbal preparation</p>	<p>Additional line of text to accommodate the input amount and form (i.e. dry extract etc) may be difficult to fit.</p>	

Document(s): *Guideline for medicine labels*

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12	1.5.2 Changing sponsor or distributor details	Bayer supports the intent of this section to allow sponsors 12 months within which to amend labelling when there is a change to the sponsor or distributor, without needing to apply for a Section 14 exemption. In practice, however due to the complexity of sponsor transfers and labelling updates often involving global headquarter involvement and dozens of products produced all over the world, it is highly unlikely that new sponsor details would appear on new labels within 12 months.	If the intent of this section is to minimise the number of S14 exemptions needed by sponsors, a 12 month default timeframe will have very little impact. Bayer suggests a 24 month timeframe provided that arrangements have been made by the sponsor or distributor companies to maintain the currency of details such as telephone numbers and addresses, through use of appropriate re-direction services. This would be a meaningful way of limiting the time and effort associated with submitting S14 exemptions to achieve compliance.

POTENTIAL REGULATORY IMPACT

1. Do the proposed amendments to the *Therapeutic Goods Orders* change any comments that you made in the 2014 consultation with respect to costings?

Yes

No

N/A

other please specify

Please provide any further comments you wish to make in the box below:

Increasing the name of the active ingredient(s) and the quantity or proportion of active ingredient(s) to 3.0 millimetres would have a significant cost burden as every single piece of product artwork would need to be redesigned.

The options for identification of declarable substances on labels for prescription and related medicines have been amended to allow a statement to direct consumers to this information in the CMI. It would create a significant cost burden if these substances had to be set out in a leaflet in the primary pack, as this would necessitate a new pack insert to be created in many instances.